

# NCI CTRP Registration Site Help Topics

Version 4.3.1

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### **This page is simply a wiki shortcut.**

This page displays subject matter that is included, in context, in many of the web pages that constitute the CTRP application user's guides.

You can send this page to a printer or convert it to a PDF, HTML, or Word document. See [Printing and Exporting Wiki Pages](#).

## Getting Help

This page contains select topics that help you to understand and use the NCI CTRP Registration application. You can find more comprehensive documentation in the [NCI CTRP Registration User's Guide](#).

- Email: [ncicbiit@mail.nih.gov](mailto:ncicbiit@mail.nih.gov)
- Call: 240-276-5541

When submitting support requests, please include:

- Your contact information, including your telephone number
- The name of the application/tool you are using
- The URL if it is a Web-based application
- A description of the problem and steps to recreate it

- The text of any error messages you have received

## Contacting the Clinical Trials Reporting Office

If you have questions or comments regarding this document, or other CTRP topics, contact the Clinical Trials Reporting Office (CTRO) at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov).

## Adding Sites

You can add your organization as a participating site to any *Abbreviated trial that meets the following criteria*:

(To add your organization as a participating site to a Complete trial, contact the lead organization.)

| Trial Attribute         | Requirement                              |
|-------------------------|--|
| Lead Organization       | Not an organization in RSS               |
| Your Organization       | Not currently participating in the trial |
| Trial Processing Status | Accepted or beyond                       |

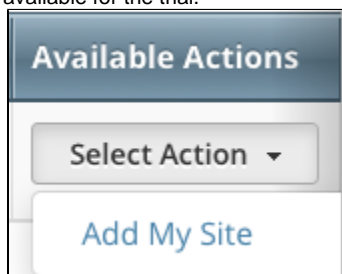
Once added, you can update your site's record at any time.

Trial information that you can update after adding your site includes the following:

- Organization's local trial identifier
- Site principal investigator
- Organization family's program codes
- Site recruitment status and dates

### How to Add Your Organization as a Participating Site

1. Select the trial that your site is participating in. The **Available Actions** column in the search results table displays actions currently available for the trial.



2. In the **Available Actions** column, click the **Select Action** button and click **Add My Site**. The Add Participating Site page appears.

Add Participating Site

NCI Trial Identifier:

NCI-2015-00165

Lead Org Trial Identifier:

FLX925-01

Title:

Phase 1/1b, First-in-Human, Dose-Escalation and Expansion Study of FLX925 Administered Orally to Subjects With Relapsed or Refractory Acute Myeloid Leukemia

Because your organization belongs to a family, you can add to this trial any site within that family. Please select the site you would like to add below:

Participating Site:\*

Mayo Clinic

Next

Cancel

The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.

- From the **Participating Site** list, select the organization that you want to add to this trial. Click **Next**. Another Add Participating Site page appears.

Add Participating Site

NCI Trial Identifier:
NCI-2015-00165

Lead Org Trial Identifier\*:
FLX925-01

Title:

Phase 1/1b, First-in-Human, Dose-Escalation and Expansion Study of FLX925 Administered Orally to Subjects With Relapsed or Refractory Acute Myeloid Leukemia

Organization Name\*:
Mayo Clinic

Local Trial Identifier\*:

Site Principal Investigator\*:

Look Up

Program Code:
Select Program Code(s)

Manage Program Codes

Note: Program Codes will be assigned to all family member organizations participating on this trial

Site Recruitment Status Date\*:
mm/dd/yyyy

Site Recruitment Status\*:
--Select--

Add Status

Please refer to the [Site Status Transition Rules](#).

Note: Site Recruitment Status of Active or Enrolling by Invitation indicates that the Site is Open for Patient Accruals. Closed to Accrual Site Status indicates that the Site is Closed to Patient Accruals.

Save

Cancel

4. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (\*) indicates a required field.

| Field                               | Description/Instructions  |
|-------------------------------------|---|
| <b>Local Trial Identifier *</b>     | Enter the identifier used at the participating site.  |
| <b>Site Principal Investigator*</b> | Click Look Up to search for, and select, the site principal investigator.   |
| <b>Program Code</b>                 | Optionally, select one or more program codes for the trial. The Program code field lists all program codes available for the organization family. |

5. Add site recruitment status information:
- Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (\*) indicates a required field.

| Field                                 | Description/Instructions   |
|---------------------------------------|--|
| <b>Site Recruitment Status Date *</b> | Enter the date on which the current trial status became effective.<br><br>To ensure that you record valid status dates, review the information provided in <a href="#">Trial Status Date Rules in the CTRP</a> . |

**Site Recruitment Status\***

Select the current stage or state of the trial or study.

The system validates all status transitions when you save a status record. If you add or update a status transition that does not conform to the rules provided in [Trial Status Transition Rules in the CTRP](#), the system displays errors and/or warnings. *Warnings* indicate that fixing the status record is optional; you do not have to resolve the transitions. However, *Errors* indicate that you must resolve the transitions by correcting trial status records.

b. Click Add Status. The Site Recruitment Status History section appears, displaying the site recruitment information you entered.

Site Recruitment Status History

Show: 10 of 1 entries

| Status Date | Status    | Comments | Validation Messages | Actions |
|-------------|-----------|----------|---------------------|---------|
| 11/04/2014  | In Review |          |                     |         |

Showing 1 to 1 of 1 entries

Save Cancel

Previous 1 Next

Site Recruitment Status- No Warnings or Errors

Site Recruitment Status History

Show: 10 of 1 entries

| Status Date | Status           | Comments | Validation Messages   | Actions |
|-------------|------------------|----------|---|---------|
| 04/03/2015  | Closed to Actual |          | <div>DEFENSE IMPROPER STATUS (ACTIVE) IS MISSING<br/>REVIEWER IS MISSING<br/>WARNING: IMPROPER STATUS (APPROVED) IS MISSING</div> |         |

Showing 1 to 1 of 1 entries

Save Cancel

Previous 1 Next

Site Recruitment Status- With Warnings and an Error

c. Repeat the process of entering a status date, entering a status, and clicking **Add Status** until you have entered all statuses for the site.

6. If the system displays Errors or Warnings indicating that the status you added is invalid, do one of the following.

a. To edit the status, in the **Actions** column, click the **Edit** icon. Then, in the **Edit Trial Status** dialog box, make changes as indicated in the Error and/or Warning message.

Edit Trial Status

Status Date:\*02/03/2015

Status:\*Enrolling by Invitation

Why Study Stopped:

1000 characters left

Administratively Complete, Withdrawn and Temporarily Closed statuses only

Comment:\*

1000 characters left

SaveCancel

b. To delete the status, in the **Actions** column, click the **Delete** icon. Enter a comment indicating the reason why you deleted the record, and then add the correct status information.

8. Click **Save**. Your information is added to the trial details.

In your role as trial owner (original submitter or current owner), you can amend only *Complete* trials. The trials you own are listed when you use the Search My Trials feature. Refer to [Searching for Trials](#). In addition to rules provided in [Registering New Trials](#), the following rules apply to amendments:

- You can create a new NIH grant record only if you can provide all of the following details:
  - Funding Mechanism
  - NIH Institution Code
  - Serial Number
  - NCI Division/Program
- You can not change the following existing information:
  - NCI trial identifier number
  - NIH grant number
  - IND/IDE serial number
- The following list is the minimum set of required documents that must be submitted with each amendment:
  - Protocol document.
  - IRB approval document.
  - A change memo document or protocol highlighted document:
    - A change memo is a document that contains a summary of changes as compared to the original, or last amended, trial submission.
    - A protocol highlighted document is a document that has been marked up, with or without using a Track Changes feature.
  - List of participating sites and contact information (for multi-site trials, if not included in the protocol document).
  - Informed consent (if not included in the protocol document) and only when there are documented changes to the consent.

When you are submitting an amendment, we recommended that you provide any additional documents that you think will be useful to the CTRO for reviewing and processing the amendment document.

A trial may have more than one owner. Review the recorded information carefully to see if another owner has modified the trial.

## Examples of Amendments

The following are examples of amendments that the Amend Trial feature accommodates.

- **Dose Escalation Amendment** (change in the number of patients treated at a given dose level)
- **Change in Sites Open to Patient Accrual**
- **Change in Principal Investigators**
- **Change in Risk to Participants** (new risk identified [new CAEPR], changes made as a result of an updated Severe Adverse Event)
- **Scientific Change** (opening an arm, adding a new arm, closing an arm, changing objectives, changing statistical analysis, adding correlative studies, increase or decrease in the accrual goal, changing from Phase I to Phase II, additional data points)
- **Correction of Typographical Errors which Change Scientific Meaning** (mg vs. mcg)
- **Eligibility Change** (change to the inclusion or exclusion criteria)
- **Therapy Change** (change in dose, adding another agent, change in administration, change in route)

## How to Amend Trials

1. On the toolbar, click **Search > Clinical Trials**.  
The Search Trials page appears.
2. Click **Search > My Trials**.  
The Search Results page displays the results of your search and actions available (if any) for each record.

| Current Processing Status | Available Actions   |
|---------------------------|---|
| Accepted                  | Select Action ▼   |
| Abstraction Response      | <div> Update<br/> <b>Amend</b><br/> Change Status<br/> View TSR<br/> View XML<br/> Verify Data </div> Select Action ▼ |

3. In the **Available Actions** column, click **Select action > Amend**.  
The Amendment Trial page displays the data currently registered with the CTRP.

## Amendment Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (\*).

XML Required, Enable "Upload from NCI CTRP" in [ClinicalTrials.gov](https://clinicaltrials.gov)? ☒ Yes ☐ No ?

[+ Expand All](#)

Amendment Details <

Trial Identifiers\* <

Other Identifiers\* <

Trial Details\* v

**Title:\***  ?

3975 characters left

**Phase:\***  ?

**Trial Type:\*** ☒ Interventional ☐ Non-interventional

**Primary Purpose:\***  ?

**Secondary Purpose:**

**Accrual Disease Terminology:**

4. In the Amendment Details section, select or enter the appropriate information in the drop-down lists and text fields. The following table describes the fields. An asterisk (\*) indicates a required field.

| Field Label             | Description/Instructions             |
|-------------------------|--------------------------------------|
| <b>Amendment Number</b> | Enter an appropriate number.         |
| <b>Amendment Date*</b>  | Select or enter an appropriate date. |

5. Select or enter the appropriate information in the remaining text fields and drop-down lists, following the instructions provided in [Registering New Trials](#).

If a trial (*Complete* or *Abbreviated*) reaches any of the following statuses, the system closes the trial at all participating sites, and sets their trial statuses to match the status of the trial that closed:

- Closed to Accrual
- Closed to Accrual and Intervention
- Administratively Complete
- Complete

The system adds a closure status to each site only if all of the following conditions are met:

- The trial has a closure status as the most recent status.
- The site status history does not have any closure status, regardless of site status date.
- The trial closure status date falls after the latest site status date.

When inserting a new participating site status record, the system performs the following actions:

- Uses the trial's closure status as the site closure status.
- Uses the trial's closure status date as the site closure status date.
- Adds the following comment in the comments field: The CTRP application automatically closed this site because the trial was closed.

The system displays the following warning if you enter any of the statuses above:

**The trial has open sites**

**▲** Since you are closing the trial, all open sites will be closed as well as a result. For your information, below is a list of currently open sites that will be affected by this operation.

Show  entries

| PO ID   | Name  | Status                  | Status Date |
|---------|---|-------------------------|-------------|
| 9772429 | Virginia Commonwealth University/Massey Cancer Center | Enrolling by Invitation | 05/06/2013  |

Showing 1 to 1 of 1 entries

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You are required to provide information for all fields marked with an asterisk (\*).

You can select a different disease code only if the trial has not accrued any subjects to date.

6. Review the amendment. See [Reviewing and Submitting Trial Amendments](#).
7. Submit the amended trial to the CTRP.

The system sends you an email notification — with the details of what has changed — whenever you amend accepted trials.

A trial can accumulate program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you amend a trial, the Program Code field displays all codes from the master list for the organization family of the lead organization.



## Converting Documents to PDF

Microsoft provides instructions for converting files to PDFs both on their [website](#) and in the Help documentation in each of its applications.

When searching for help, use the search term "save file as pdf".

You don't need a document converter in Mac OSX. Instead, *print* your documents to a PDF file.

### How to Convert Text-Based Files to PDFs in Mac OSX

1. Open your text file in its original format (.doc, .xls, etc.)
2. Click **File > Print**.
3. In the **Print** window, click the **PDF** button at the bottom-left and select the **Save as PDF** option.
4. Choose the location, rename your PDF file, and then click **Save**.

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## Displaying Trial Ownership

As a site administrator, you can display trial ownership for any trial owned by your site for which your organization or its family member organization is the lead organization. Trial owners can view trial details, update trials, and amend *Complete* trials. Additionally, you can indicate whether a user would like to receive system notifications, including TSRs and XML files, on a trial-by-trial basis.

### TSR and XML distribution

Trial owners can access TSR and XML documents.

### How to Display Trial Ownership

1. On the toolbar, click **Administration > Trial Ownership > View**.  
The Display Trial Ownership page displays the current owner(s) of the trials for which your organization is the lead organization. It also indicates which of the owners, for each of the trials, will receive system-generated email notifications.

### Display Trial Ownership

☐ Hide Search Criteria

First Name:

Last Name:

E-Mail:

NCI Identifier:

#### Search Results

Show

Search:

<< < 1 > >>

| First Name | Last Name | E-Mail                | NCI Identifier | Lead Org ID | Receive Email?   | Action                                |
|------------|-----------|-----------------------|----------------|-------------|--|---------------------------------------|
| Isabelle   | Autissier | anthonel@mail.nih.gov | NCI-2014-00508 | 123456ABC   | <input type="button" value="Yes"/> <input type="button" value="No"/> | <input type="button" value="Remove"/> |

Showing 1 to 1 of 1

<< < 1 > >>

2. To display all the trials owned by a given user, search for the user by first name, last name, or email address, and then click **Search**.  
All trials owned by the user are listed in the Search Results list.
3. To display all owners of a given trial, enter the NCI Identifier in the field provided, and then click **Search**.  
All owners of the selected trial are listed in the Search Results list.

#### **You can filter the search results and create more space to display the results**

To filter the search results, in the **Search** field, type one or more characters contained in any of the fields. The list is filtered as you type subsequent characters. For details, refer to [Working with Tables and Search Results](#) .

To create more space on the page, on the upper right corner of the page, select the **Hide Search Criteria** check box.

4. To indicate whether or not an owner of a trial should receive system-generated email messages, in the **Receive Email?** column, select **Yes** or **No**.

Selecting **Yes** indicates that the owner will receive *all* notifications regarding the specified trial.

Selecting **No** indicates that the owner will *not* receive any notifications regarding the specified trial.

5. To revoke ownership of a trial, locate the user/trial in the **Search Results** list, and then click **Remove**.

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## **Editing Trial Details**

You can edit your updated trial details after you have reviewed them at any time before you submit them to the CTRP.

### **How to Edit Updated Details**

1. Scroll to the bottom of the **Review Trial** Details page, and click **Edit**.

The Update Trial page displays all information you have provided, in editable form.

2. Make changes as necessary and then follow the instructions in [Reviewing and Submitting Trial Updates](#) .

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## **Granting and Revoking Administrative Authority**

The relationships between administrators and trials in a single organization are as follows:

- An organization can have the following:
  - One original site administrator
  - Many site administrators appointed by the original administrator
  - Many trials, providing that the organization plays the lead organization role
  - Many users affiliated with the site who can submit and own trials
- A trial can have the following:
  - One submitter
  - One organization affiliation, defined by the lead organization
  - Many trial owners

Site administrators are trial owners by default if the site administrator's affiliated organization is the trial's lead organization. A site administrator can be added explicitly as an owner of any trial. Refer to [Managing Trial Ownership](#) .

- A site administrator can do the following:
  - Display trial ownership
  - Manage trial ownership
  - Manage site record ownership
  - Manage Accrual access
  - Manage the administrative rights of other users in the organization
  - Revoke own administrative rights

#### **Site administrators do not receive system-generated emails automatically**

System-generated emails (including TSRs) are sent to a site administrator only if the site administrator's affiliated organization is the trial's lead organization, or if the site administrator is the trial submitter and/or trial owner. The site administrator can also [manage email notification globally](#) on the *My Account* page.

As a site administrator, you can grant and revoke administrative rights to other users in your organization. (You can grant/revoke administrative authority to users who have a CTRP account and whose organizational affiliation is the same as your own.) Site administrators are the only Registration users who can see and access the Site Administration menu.

How to Grant and Revoke Site Administrator Rights

1. On the toolbar, click **Administration > Site Administration**.  
The Site Administration page appears, listing the administrators to whom administrator rights have previously been granted, if applicable.

Site Administration

First Name:

Last Name:

E-Mail:

Hide Search Criteria

Search

Reset

Search Results

| First Name | Last Name  | E-Mail                | Allow as Site Admin?                |
|------------|------------|-----------------------|-------------------------------------|
| Isabelle   | Autissier  | anthonel@mail.nih.gov | <input checked="" type="checkbox"/> |
| Laura      | Stackhouse | example@example.com   | <input type="checkbox"/>            |
| Teresa     | Melton     | example@example.com   | <input type="checkbox"/>            |
| Valerie    | Kordowski  | example@example.com   | <input type="checkbox"/>            |

Save

2. Search for the Registration user for whom you want to adjust administrative rights: specify the user by first name, last name, or email address, and then click **Search**. The user's name appears in the Search Results list.

a. To promote the user to site administrator, select the check box in the **Allow as Site Admin?** column.

As a site administrator you can revoke your own administrative rights. Use caution if you do so because you can not promote yourself thereafter.

- b. To revoke administrative access, clear the check box under the **Allow as Site Admin?** column.

3. Click **Save**.

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Managing Access to the Subject Accrual Application

Site Administrators can authorize users to submit subject accrual data for trials that have been fully abstracted and verified. Once assigned, users can submit accrual data for all trials associated with their affiliated organization or organization family members. For *Complete* trials (National, Externally Peer-Reviewed, or Institutional), the organization must be a lead; for *Abbreviated* trials (Industrial), the organization must be a participating site.

Assignment at the organization level pertains to trials that the organization has registered in CTRP and extends to those that it will register in the future. Similarly, assignment at the organization family level pertains to trials that any member organization has registered in CTRP and extends to those that it will register in the future.

Access to CTEP and DCP trial accruals is restricted to the CTRO only.

The table below outlines the access and trial assignment rules for *Complete* and *Abbreviated* trials.

| Access/Assignment  | Complete Trial   | Abbreviated Trial   |
|--|--|---|
| Who can assign access?   | <ul style="list-style-type: none"><li>A registered user logged in as the Lead Organization's Site Administrator for any trial other than DCP or CTEP trials</li><li>Super Abstractor for DCP and CTEP trials</li></ul>   | <ul style="list-style-type: none"><li>A registered user logged in as Site Administrator for any trial other than DCP or CTEP trials</li><li>Super Abstractor for DCP and CTEP trials</li></ul>  |
| Who can be assigned access?  | Any registered user affiliated with the Site Administrator's organization, or family member organization (including the Site Administrator)  | Any registered user affiliated with the assigner's organization (including the site administrator)  |
| What types of trials can be assigned?  | Complete trials for which the assigner's organization is the lead organization   | Abbreviated trials for which the assigner's organization is the Lead Organization or participating site   |
| How is access assigned?  | <ul style="list-style-type: none"><li>By trial</li><li>By Organization</li><li>By Organization Family member</li></ul> <p>The system automatically assigns the Organization Family Accrual Submitter access to any trial registered by new organizations added to an organization family in the future. It withdraws access if the Organization Family Accrual Submitter's organization is removed from the organization family in the future.</p> | <ul style="list-style-type: none"><li>By trial</li><li>By participating site</li></ul>  |
| Who can submit accrual data?   | Any assigned user, for any organization trials for which the assigner's organization is the Lead Organization  | Any assigned user affiliated with the participating site  |
| Which trials can the Organization Family Accrual Submitter submit accrual data to? | <ul style="list-style-type: none"><li>All complete trials registered by the submitter's organization or family member organization</li><li>Trials currently registered in CTRP</li><li>Trials that the organization registers in CTRP in the future, once abstracted</li></ul>   | <ul style="list-style-type: none"><li>All abbreviated trials registered by the submitter's participating site <i>only</i></li><li>Trials currently registered in CTRP</li><li>Trials that the organization registers in CTRP in the future, once abstracted</li></ul> |

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## Managing Participating Site Record Ownership

### How to Assign and Unassign Trial Ownership

1. On the toolbar, click **Administration > Trial Ownership > Manage**.

The Manage Trial Ownership page displays the names of your affiliated organization or it's family member organization(s) users on the top of the page, and trials that your organization owns as a Lead Organization or Participating Site below the list of names.

## Manage Trial Ownership

Manage trial record ownership for: (select one)

- ☒ Trials where the **Lead Organization** is from affiliated Organization's family. (includes only Complete trials)
- ☐ Trials where a **Participating Site** is from affiliated Organization's family. (includes only Abbreviated trials)

### Users affiliated with this site (M D Anderson Cancer Center)

Select this check box to select or deselect all users

Search:

| <input type="checkbox"/> | Name                | E-Mail                |
|--------------------------|---------------------|-----------------------|
| <input type="checkbox"/> | Morgan, Michelle    | example@example.com   |
| <input type="checkbox"/> | Kratz, Anna         | example@example.com   |
| <input type="checkbox"/> | Autissier, Isabelle | anthonel@mail.nih.gov |

2. Under **Manage trial ownership for**, select which role your affiliated organization or its family member organization(s) play(s).
  - a. For *Complete* trials, select **Lead Organization**.
  - b. For *Abbreviated* trials, select **Participating Site**.
3. To indicate which users will have the ability to update and amend selected *Complete* trials; or update *Abbreviated* trials, select one or more user names on the list.

#### You can select or deselect all names, or filter the list of names

To select all names, select the check box on the left side of the column heading. Click it again to deselect all names.

To filter the list of names, in the **Search** field, type one or more characters contained in a user's name or email address. The list is filtered as you type subsequent characters.

4. In the list of trials at the bottom of the page, under **All Available Trials**, or **All Abbreviated Trials**, select the trials to assign to the user(s), and then click the **Assign** icon ( > ).

### Trials where this site is the Lead Organization

A record owner of a trial listed below can amend or update that trial in CTRP

| All Available Trials         |                |
|------------------------------|----------------|
| Search: <input type="text"/> |                |
| <input type="checkbox"/>     | NCI Identifier |
| <input type="checkbox"/>     | NCI-2014-00454 |
| <input type="checkbox"/>     | NCI-2014-00499 |

Showing 1 to 2 of 2 entries

Assign



Unassign



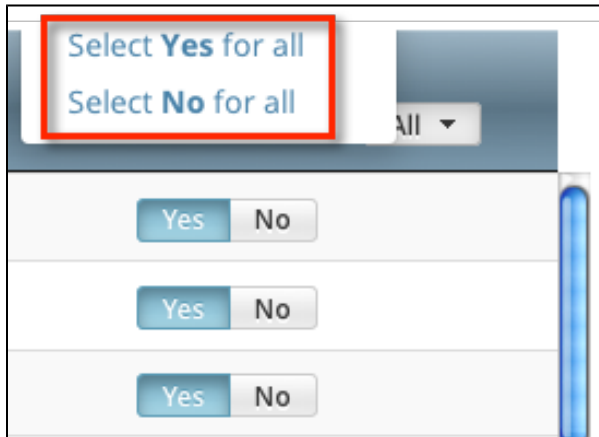
| Trial Owner Assignments      |                                 |                |                 |
|------------------------------|---------------------------------|----------------|-----------------|
| Search: <input type="text"/> |                                 |                |                 |
| <input type="checkbox"/>     | Name                            | NCI Identifier | Lead Org ID     |
| <input type="checkbox"/>     | National Cancer Institute, xxxx | NCI-2014-00454 | LeadMay21       |
| <input type="checkbox"/>     | Anthone, Lauren                 | NCI-2014-00454 | LeadMay21       |
| <input type="checkbox"/>     | Autissier, Isabelle             | NCI-2014-00499 | LEADORGID 123 K |

Showing 1 to 3 of 3 entries

5. To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the **Unassign** icon ( < ).
6. For *Complete* trials, indicate which trial owners should receive email notifications about the trial(s):
  - In the **Email Notifications?** column, click the **Yes** or **No** button.

|                          | Name                | NCI Identifier | Lead Org ID     | Email Notification? | All ▾ |
|--------------------------|---------------------|----------------|-----------------|---------------------|-------|
| <input type="checkbox"/> | Anthone, Lauren     | NCI-2014-00454 | LeadMay21       | Yes No              |       |
| <input type="checkbox"/> | Autissier, Isabelle | NCI-2014-00499 | LEADORGID 123 K | Yes No              |       |

- To indicate that all owners should receive/not receive email, in the **Email Notification** column header, click **All > Select Yes/No for all**.



The **Select No for All** and **Select Yes for All** options apply globally to all trial owners, not just the ones currently visible in the list.

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## Managing Program Codes

Each cancer center family uses program codes to group its clinical trials. As a site administrator, you can manage the set of program codes and program code assignments for your organization family. You can assign program codes to trials that meet all of the following criteria:

- Complete trials with a lead organization as a member of your cancer center family of organizations, or Abbreviated trials where such a member is a participant.
- Trials with status other than Withdrawn.
- Trials with processing status other than Rejected or Submission Terminated.
- Trials that were active during the cancer center reporting period.

Keep in mind the following points about the entities in CTRP that represent NCI-designated Cancer Centers:

- A CTRP organization family represents an NCI-designated Cancer Center family of organizations. For brevity, this guide refers to this entity as a *Cancer Center family*, a *Cancer Center*, or an *organization family*.
- A CTRP organization that is a member of a Cancer Center family is considered a Cancer Center organization. For brevity, this guide refers to this entity as a *Cancer Center organization*.

## Using the Manage Program Codes Master List Page

### Viewing Program Codes

- On the toolbar, click **Administration > Program Codes > Manage Master List**. The Manage Program Codes Master List appears.

## Manage Program Codes Master List

Organization

Family: Cancer Center

| Program Code *       | Program Name         |                                     |
|----------------------|----------------------|-------------------------------------|
| <input type="text"/> | <input type="text"/> | <button>+ Add Program Code</button> |

Show 10 ▾

Search:

<< < 1 2 > >>

| Program Code ▲ | Program Name                                    |   |
|----------------|---|---|
| 1              | Cell Biology                                    |          |
| 2              | Developmental Therapeutics                      |          |
| 3              | Gene and Virus Therapy                          |          |
| 4              | Cancer Immunology and Immunotherapy             |          |
| 5              | Gastrointestinal Cancer                         |          |
| 6              | Hematologic Malignancies                        |          |
| 7              | Neuro-oncology                                  |       |
| 8              | Women's Cancer                                  |    |
| 9              | Cancer Prevention and Control (CPC)             |    |
| 10             | Genetic Epidemiology and Risk Assessment (GERA) |    |

Showing 1 to 10 of 11

<< < 1 2 > >>

Excel CSV

2. Notice that this page displays information specific to your organization family.

You can navigate through the list of program codes just like any other list of search results in the CTRP Registration application. For instructions, refer to [Working with Tables and Search Results](#).

### Adding Program Codes

1. On the Manage Program Codes Master List page, in the **Program Code** field, enter a unique program code. This is likely to be a very short representation of the program.

| Program Code *       | Program Name         |                                     |
|----------------------|----------------------|-------------------------------------|
| <input type="text"/> | <input type="text"/> | <button>+ Add Program Code</button> |

2. (Optional) In the **Program Name** field, enter a program name.
3. Click **Add Program Code**. The new program code appears in the list.

For each organization family, active program codes must be unique. The list may contain two entries with the same program code, if one is active and the other is inactive.

### Editing Program Codes

When you change a program code, the system re-assigns to the new program code all trials (including closed trials) currently assigned to the old program code.

1. On the Manage Program Codes Master List page, in the row for the program code of interest, click the Edit icon (



). The Edit Program Code dialog box appears.

Edit Program Code

Organization Family of Affiliate Site: Mayo Clinic Cancer Center

Program Code:

1

Program Name:

Name1

Warning: Modifying the program code will cause all trials currently assigned to the old program code to be reassigned to the new program code. The old code will be permanently removed.

Save

Cancel

2. Change the program code, program name, or both.
3. Click **Save**.
  - If you have changed only the program name, the list reflects your change.
  - If you have changed the program code, a confirmation message appears. If you want to proceed, click **Yes**. The list reflects your change.

## Deleting or Inactivating Program Codes

1. On the Manage Program Codes Master List page, in the row for the program code of interest, click the Delete icon (



). The system checks whether the selected program code has been assigned to any trials. What happens next depends on the result of that system check:

- If the selected program code has not been assigned to any trials, then a message appears, asking you to confirm the deletion.

Confirm Delete

The following program code is not assigned to any trial, and will be permanently deleted:

3 - Immunobiology

Please confirm.

Delete

Cancel

- Otherwise, a dialog box appears with details, asking you to confirm the inactivation.



**Inactivate Program Code Confirmation** ✕

The following program code is assigned to one or more trial(s):

**15 - Hematologic Malignancies**

Inactivating this program code will:

- Unassign it from all trials that were active during the reporting period (see list below), and
- Make it no longer available to assign to trials

Note that only trials that were active at any time during the reporting period will be affected. The reporting period for your center is 1/1/2015 to 12/31/2015.

---

Show ▼

Search:

<< < 1 > >>

| Trial ID(s) ▼  | Title   | Lead Organization                   | Principal Investigator   | Trial Status | Program Code(s) |
|----------------|---|-------------------------------------|--------------------------|--------------|-----------------|
| NCI-2014-01652 | Role of SAP/SH2D1A in NKT Cell Development and Activation | Children's Hospital of Philadelphia | <del>Michael, John</del> | Active       | 15              |

Showing 1 to 1 of 1

<< < 1 > >>


---

Are you sure you would like to proceed with this action?

Yes
No

2. After reading the provided information, confirm or cancel the action:
  - To confirm deletion, click **Delete**. To confirm inactivation, click **Yes**. The list changes to reflect your action:
    - If you deleted a program code, the system removes the program code completely.
    - If you inactivated a program code, the system removes the program code from *only* trials that were active at any time during the reporting period. The program code remains in the Master List with "-inactive" appended, but you can no longer assign it to trials.
  - To cancel deletion, click **Cancel**. To cancel inactivation, click **No**.

## Viewing the Assignments for a Program Code

1. On the Manage Program Codes Master List page, in the row for the program code of interest, click the View icon (  ). The Manage Program Code Assignments page appears.

## Manage Program Code Assignments

Organization Family: Mayo Clinic Cancer Center

Reporting Period End Date: 12/31/2016

Reporting Period Length (months): 2

The following trials were active during the specified reporting period:

Show 10

Search:

| Trial ID(s)                 | Title   | Lead Organization  | Principal Investigator | Trial Status | Program Code(s) |
|-----------------------------|---|--|------------------------|--------------|-----------------|
| NCI-2015-01618, NCT02303990 | RADVAX: A Stratified Phase I Trial of Pembrolizumab with Hypofractionated ... | University of Pennsylvania/Abramson Cancer Center<br><a href="#">Show my participation</a> | Mulligan, David        | Active       | 12              |

Showing 1 to 1 of 1

[Excel](#) [CSV](#)

Please select an action button to modify program code assignments for the selected trials in the table above.

[+ Assign](#) [- Unassign](#) [⇄ Replace](#)

- Notice that this page displays information specific to a date range:
  - The default end date is 12/31/2015. In the **Reporting Period End Date** field, consider specifying a different date.
  - The default reporting period length is 12 months. In the **Reporting Period Length** field, consider specifying a different number.
- Notice that this page displays a list of trials that meet all the following criteria:
  - Trials in which any member of your organization family is a participant.
  - Trials assigned the program code that you selected on the Manage Program Codes Master List page.
  - Trials with any of the following statuses at any time within the reporting period, as specified on this page:
    - In Review
    - Approved
    - Active
    - Enrolling by Invitation
    - Temporarily Closed to Accrual
    - Temporarily Closed to Accrual and Interventions
- If you want to filter the list, click the filter icon (



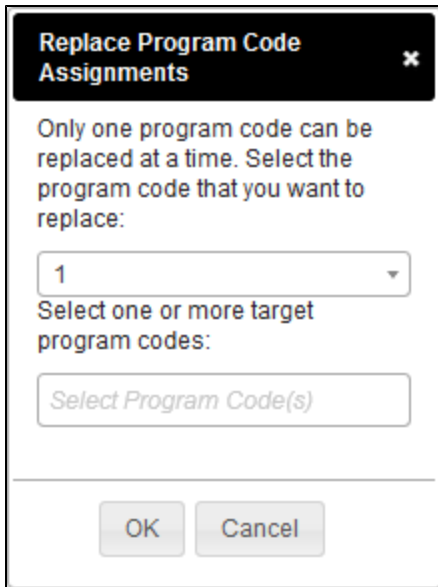
) in the Program Code(s) column. The Select Program Code(s) button appears. Click **Select Program Code(s)**. The list includes all program codes and other options. Select one or more program codes from the list. (To select all program codes or deselect all program codes, toggle the **Select/Deselect All** option. To display trials that have not been assigned to program codes, select **None**.) The system updates the list of trials to reflect your selections.

You can navigate through the list of trials just like any other list of search results in the CTRP Registration application. For instructions, refer to [Working with Tables and Search Results](#). On the Program Code Assignments page, in the search box, if you include the search term in double quote marks (for example "cancer"), the search results include trials that have an exact match in any of the first five columns.

## Using the Manage Program Code Assignments Page

### Replacing a Program Code

- On the Manage Program Code Assignments page, select one or more trials that have been assigned to program codes.
- Click **Replace**. The Replace Program Code Assignments dialog box appears with two lists. The first list includes all program codes assigned to any selected trial.



**Replace Program Code Assignments** ✕

Only one program code can be replaced at a time. Select the program code that you want to replace:

1 ▾

Select one or more target program codes:

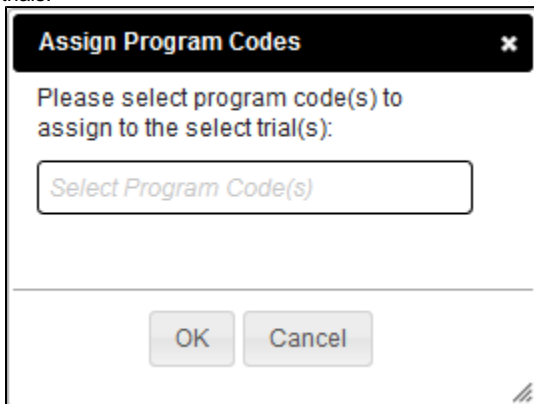
Select Program Code(s)

OK Cancel

3. In the first list, select the program code that you want to replace.  
The second list includes all program codes for the organization family. However, the one you selected in the first list becomes unavailable for selection in the second list.
4. In the second list, select one or more target program codes.
5. Click **Replace**. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

## Assigning Program Codes to Multiple Trials

1. On the Manage Program Code Assignments page, select one or more trials of interest.
2. Click **Assign**. The Assign Program Codes dialog box appears. The list includes all program codes that can be assigned to the selected trials.



**Assign Program Codes** ✕

Please select program code(s) to assign to the select trial(s):

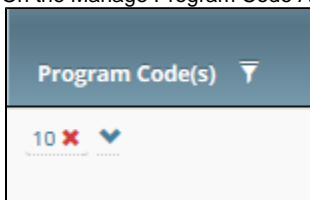
Select Program Code(s)

OK Cancel

3. In the list, select one or more target program codes.
4. Click **Assign**. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

## Assigning a Program Code to a Single Trial

1. On the Manage Program Code Assignments page, in the row for the trial of interest, in the **Program Code(s)** column, click the v icon.



Program Code(s) ▼

10 ✕ ♥

The Program Code field appears.

2. Click the **Program Code** field. The list includes all program codes, but the ones already assigned to the selected trial are unavailable for selection.
3. Select the target program code. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

You can also assign a program code to a trial while performing the following tasks:

- Registering, amending, or updating a Complete trial. For instructions, refer to [Registering New Trials](#), specifically [Recording Data Table 4 Information](#).
- Adding your site after importing a trial. For instructions, refer to [Registering Abbreviated \(Industrial and Other\) Trials](#).
- Adding a participating site to an Abbreviated trial or updating such a site (as a site affiliate). For instructions, refer to [Adding Your Site to Abbreviated Trials](#).
- Adding participating sites to Abbreviated trials (as a site administrator). For instructions, refer to [Adding Sites](#).

## Unassigning Program Codes from Multiple Trials

1. On the Manage Program Code Assignments page, select one or more trials that have been assigned to program codes.
2. Click **Unassign**. The Unassign Program Codes dialog box appears with a list of all program codes, but only the ones assigned to the selected trials are available for selection.

3. In the list, select one or more program codes.
4. Click **Unassign**. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

## Unassigning a Program Code from a Single Trial

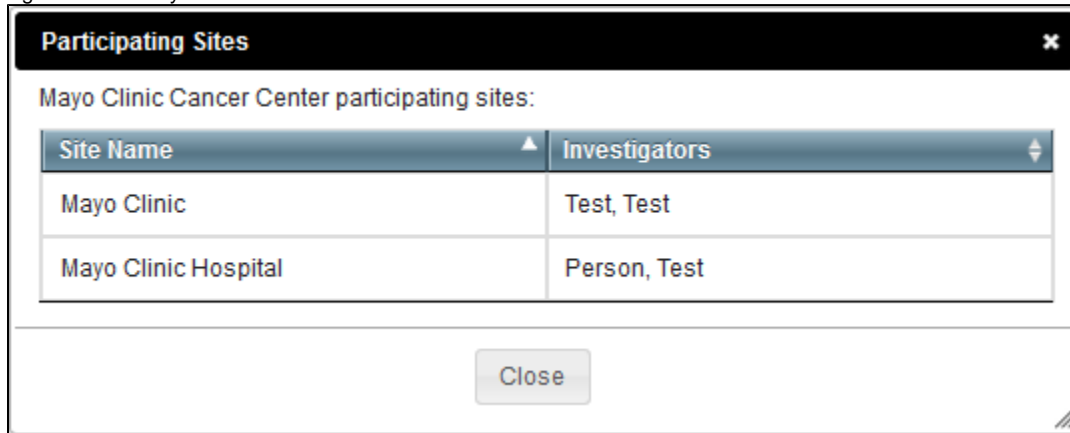
On the Manage Program Code Assignments page, in the row for the trial of interest, in the **Program Code(s)** column, click the **x** for the program code you want to unassign. The Program Code(s) column reflects your changes.

You can also unassign a program code to a trial while performing the following tasks:

- Amending or updating a Complete trial. For instructions, refer to [Registering New Trials](#), specifically [Recording Data Table 4 Information](#).
- Adding a participating site to an Abbreviated trial or updating such a site (as a site affiliate). For instructions, refer to [Adding Your Site to Abbreviated Trials](#).
- Adding participating sites to Abbreviated trials (as a site administrator). For instructions, refer to [Adding Sites](#).

## Viewing Your Participation

1. On the Manage Program Code Assignments page, in the row for the trial of interest, in the **Lead Organization** column, click **Show my participation**. The Participating Sites dialog box appears, listing only the participating organizations that are members of your organization family.



The dialog box titled "Participating Sites" has a close button (X) in the top right corner. Below the title bar, it says "Mayo Clinic Cancer Center participating sites:". There is a table with two columns: "Site Name" and "Investigators".

| Site Name            | Investigators |
|----------------------|---------------|
| Mayo Clinic          | Test, Test    |
| Mayo Clinic Hospital | Person, Test  |

At the bottom of the dialog box is a "Close" button.

2. When you are done viewing the list of participating sites, click **Close**.

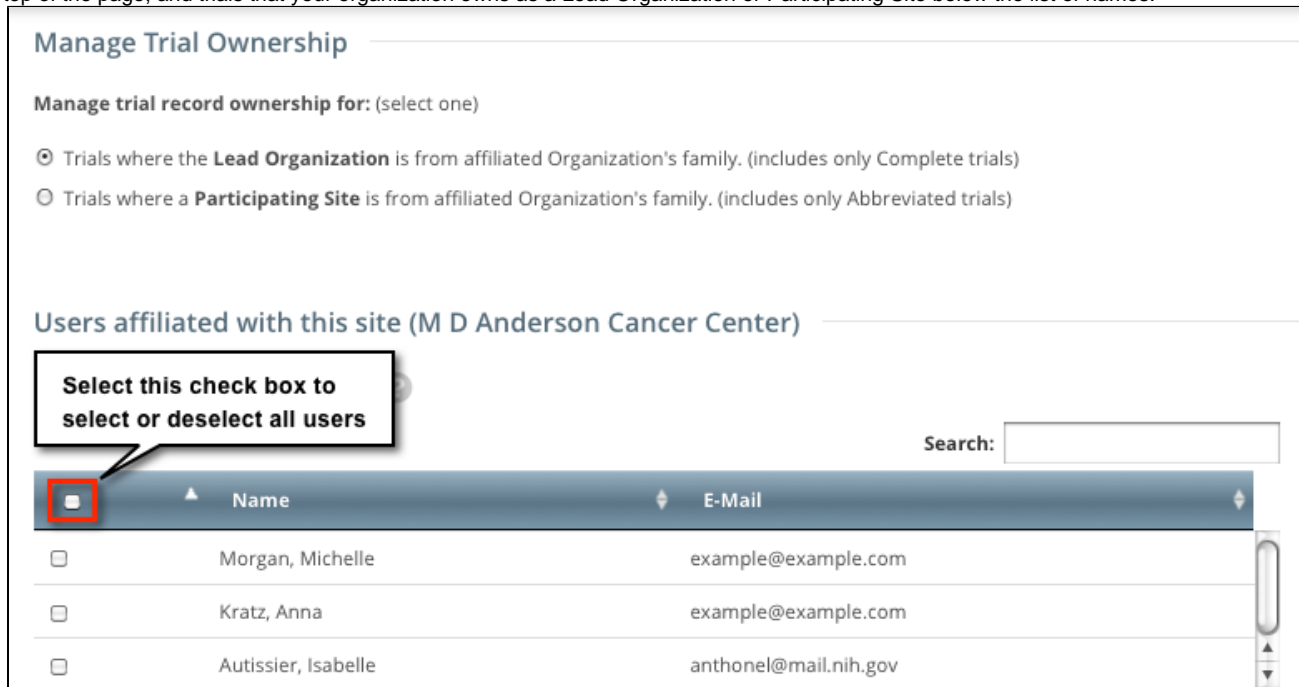
[Return to top of page](#)

## Managing Trial Ownership

### How to Assign and Unassign Trial Ownership

1. On the toolbar, click **Administration > Trial Ownership > Manage**.

The Manage Trial Ownership page displays the names of your affiliated organization or its family member organization(s) users on the top of the page, and trials that your organization owns as a Lead Organization or Participating Site below the list of names.



The "Manage Trial Ownership" page has a title bar and a section for "Manage trial record ownership for: (select one)". There are two radio buttons: "Trials where the **Lead Organization** is from affiliated Organization's family. (includes only Complete trials)" and "Trials where a **Participating Site** is from affiliated Organization's family. (includes only Abbreviated trials)".

Below this is a section titled "Users affiliated with this site (M D Anderson Cancer Center)". There is a search bar and a table of users. A callout box points to a checkbox in the first column of the table, stating "Select this check box to select or deselect all users".

|                          | Name                | E-Mail                |
|--------------------------|---------------------|-----------------------|
| <input type="checkbox"/> | Morgan, Michelle    | example@example.com   |
| <input type="checkbox"/> | Kratz, Anna         | example@example.com   |
| <input type="checkbox"/> | Autissier, Isabelle | anthonel@mail.nih.gov |

2. Under **Manage trial ownership for**, select which role your affiliated organization or its family member organization(s) play(s).
  - a. For *Complete* trials, select **Lead Organization**.
  - b. For *Abbreviated* trials, select **Participating Site**.
3. To indicate which users will have the ability to update and amend selected *Complete* trials; or update *Abbreviated* trials, select one or more user names on the list.

### You can select or deselect all names, or filter the list of names

To select all names, select the check box on the left side of the column heading. Click it again to deselect all names.

To filter the list of names, in the **Search** field, type one or more characters contained in a user's name or email address. The list is filtered as you type subsequent characters.

4. In the list of trials at the bottom of the page, under **All Available Trials**, or **All Abbreviated Trials**, select the trials to assign to the user(s), and then click the **Assign** icon ( > ).

**Trials where this site is the Lead Organization**

A record owner of a trial listed below can amend or update that trial in CTRP

**All Available Trials**

Search:

| <input type="checkbox"/> | NCI Identifier | Lead Org ID     |
|--------------------------|----------------|-----------------|
| <input type="checkbox"/> | NCI-2014-00454 | LeadMay21       |
| <input type="checkbox"/> | NCI-2014-00499 | LEADORGID 123 K |

Showing 1 to 2 of 2 entries

Assign >

Unassign <

**Trial Owner Assignments**

Search:

| <input type="checkbox"/> | Name                            | NCI Identifier | Lead Org ID     | Email Notification?  |
|--------------------------|---------------------------------|----------------|-----------------|--|
| <input type="checkbox"/> | National Cancer Institute, xxxx | NCI-2014-00454 | LeadMay21       | <input type="button" value="Yes"/> <input type="button" value="No"/> |
| <input type="checkbox"/> | Anthone, Lauren                 | NCI-2014-00454 | LeadMay21       | <input type="button" value="Yes"/> <input type="button" value="No"/> |
| <input type="checkbox"/> | Autissier, Isabelle             | NCI-2014-00499 | LEADORGID 123 K | <input type="button" value="Yes"/> <input type="button" value="No"/> |

Showing 1 to 3 of 3 entries

5. To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the **Unassign** icon (<).
6. For **Complete** trials, indicate which trial owners should receive email notifications about the trial(s):
  - In the **Email Notifications?** column, click the **Yes** or **No** button.

| <input type="checkbox"/> | Name                | NCI Identifier | Lead Org ID     | Email Notification?  |
|--------------------------|---------------------|----------------|-----------------|--|
| <input type="checkbox"/> | Anthone, Lauren     | NCI-2014-00454 | LeadMay21       | <input type="button" value="Yes"/> <input type="button" value="No"/> |
| <input type="checkbox"/> | Autissier, Isabelle | NCI-2014-00499 | LEADORGID 123 K | <input type="button" value="Yes"/> <input type="button" value="No"/> |

- To indicate that all owners should receive/not receive email, in the **Email Notification** column header, click **All > Select Yes/No for all**.

**Select Yes for all**

**Select No for all**

All ▾

|  |
|--|
| <input type="button" value="Yes"/> <input type="button" value="No"/> |
| <input type="button" value="Yes"/> <input type="button" value="No"/> |
| <input type="button" value="Yes"/> <input type="button" value="No"/> |

The **Select No for All** and **Select Yes for All** options apply globally to all trial owners, not just the ones currently visible in the list.

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## Managing Who Can View Reports

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## Managing Your Account

You can update your account information after you have registered for an account and have logged in to Registration.

### Changing your Organizational Affiliation results in loss of privileges

If you change your organizational affiliation, the system revokes your existing Site Admin and Accrual Submission privileges.

### How to Edit Your Account Information

1. On the top right corner of any page, click **Your Username > My Account**.  
The My Account page appears, populated with the information you previously supplied for your account.
2. In the **Your Account Profile** section, make any changes as necessary, and then click **Save**.

### Keep your account up to date

The PRS organization name is required for uploading trial records to ClinicalTrials.gov via a system-generated file. The PRS organization name you include in your profile is included in that file. This precludes having to update the PRS name in the file. Therefore it is very important for you to update your account whenever there is a change in PRS.

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## Registering Industrial and Other Trials

You can register Industrial/Other trials in the CTRP by importing them directly from ClinicalTrials.gov. You must enter a ClinicalTrials.gov Identifier (NCT ID) for each trial you register. If the trial you want to register does not have an NCI ID, or if you do not know it, contact the CTRO for assistance at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov).

The system registers the trials you import from ClinicalTrials.gov as *Abbreviated* trials. To classify a trial as "Other", contact the Clinical Trials Reporting Office staff at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov) after importing/registering the trial in the CTRP system.

For more information about Data Table 4 categorization, see [Guidelines for Abbreviated Trials](#).


### How to Register Industrial Trials

1. On the toolbar, click **Register Trial**, and select **Industrial/Other**.

To read a definition of each of the trial submission categories (study sources), click **View Trial Category Definitions**, or, click the Help icon (



) next to each category.


|  |   |
|--|---|
| Register Trial ▾   |   |
| National   | ? |
| Externally Peer-Reviewed   | ? |
| Institutional  | ? |
| Industrial/Other   | ? |
| View Category Definitions  | ? |
|  Batch Upload |   |

The Import ClinicalTrials.gov Trials page appears.

## Import ClinicalTrials.gov Trials

To register a trial under the Industrial/Other submission category in CTRP, please enter the ClinicalTrials.gov identifier below and click **Search Studies**. If you do not have the ClinicalTrials.gov identifier or if the trial does not have one yet then please contact CTRO staff at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov).

ClinicalTrials.gov Identifier:

 Search Studies

**Note:** Any trials imported using this feature will be registered as Abbreviated in CTRP system. If the trial should be classified as "Other" then please contact the Clinical Trials Reporting Office staff at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov) after importing/registering this trial in the CTRP system.

2. Enter the ClinicalTrials.gov Identifier, and then click **Search Studies**.

The system searches for the ID you entered. If it finds a match in the CTRP, you can not import the trial.

3. If the system does not find a match in the CTRP, the trial record from ClinicalTrials.gov appears.




## Import ClinicalTrials.gov Trials

No match was found in CTRP system using the ClinicalTrials.gov identifier specified. However, a match has been found in ClinicalTrials.gov. Please review the following trial details and click 'Import Trial From ClinicalTrials.gov' button if you wish to proceed and register this trial in CTRP system. Otherwise, click 'Cancel' to stop.

## Studies on ClinicalTrials.gov

One item found.<sup>1</sup>

| ClinicalTrials.gov Identifier | Status     | Study   |
|-------------------------------|------------|---|
| NCT01744106                   | Recruiting | <p>A Multicenter, Randomized, Placebo-Controlled Study of Pseudoephedrine for the Temporary Relief of Nasal Congestion in Children With the Common Cold</p> <p><b>Condition(s):</b> Nasal Congestion Associated With the Common Cold<br/><b>Intervention(s):</b> Drug: pseudoephedrine hydrochloride 30 mg tablets; Drug: Placebo tablets</p> |

 Import Trial From ClinicalTrials.gov

 Cancel

- Click **Import Trial From ClinicalTrials.gov**.

While it is possible for two users to attempt to import a trial at the exact same time, the system cannot process simultaneous imports. If you receive an error message the first time you attempt to import a trial, wait a short while, and then try again.

The trial is registered in the CTRP and assigned a unique NCI identifier with the processing status Submitted. The system synchronizes the imported record in the CTRP with the one in ClinicalTrials.gov.

## Trial Details

**Message:** Trial NCT01106534 has been imported and registered in CTRP system successfully. A unique NCI identifier NCI-2014-00491 has been assigned to this trial with a processing status of Submitted. Once the CTRO staff validates and accepts this trial, you will be able to add your site to the trial via CTRP Registration application. Please contact CTRO staff for any further assistance.

 Add My Site

## Trial Identifiers

**NCI Trial Identifier:** NCI-2014-00491

**Lead Organization** 06-374C

**Trial Identifier:**

## Trial Details

**Title:** XIENCE V® Everolimus Eluting Coronary Stent System USA Post- Approval Study (XIENCE V® USA DAPT Cohort) (XVU-AV DAPT)

**Phase:** IV

**Trial Type:** Interventional

**Primary Purpose:** Treatment

**Secondary Purpose:**

- To add your site as a participant in the trial, click **Add My Site**. The Add Participating Site page appears.

Add Participating Site

NCI Trial Identifier:

NCI-2015-00165

Lead Org Trial Identifier:

FLX925-01

Title:

Phase 1/1b, First-in-Human, Dose-Escalation and Expansion Study of FLX925 Administered Orally to Subjects With Relapsed or Refractory Acute Myeloid Leukemia

Because your organization belongs to a family, you can add to this trial any site within that family. Please select the site you would like to add below:

Participating Site:

Mayo Clinic

Next

Cancel

The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.

- From the **Participating Site** list, select the organization that you want to add to this trial. Click **Next**. Another Add Participating Site page appears.

Add Participating Site

NCI Trial Identifier: NCI-2015-00165

Lead Org Trial Identifier:\* FLX925-01

Title: Phase 1/1b, First-in-Human, Dose-Escalation and Expansion Study of FLX925 Administered Orally to Subjects With Relapsed or Refractory Acute Myeloid Leukemia

Organization Name:\* Mayo Clinic

Local Trial Identifier:\*

Site Principal Investigator:\*

Look Up

Program Code: Select Program Code(s)

Manage Program Codes

Note: Program Codes will be assigned to all family member organizations participating on this trial

Site Recruitment Status Date:\*

Site Recruitment Status:\*

mm/dd/yyyy

--Select--

Add Status

Please refer to the [Site Status Transition Rules](#).

Note: Site Recruitment Status of Active or Enrolling by Invitation indicates that the Site is Open for Patient Accruals. Closed to Accrual Site Status indicates that the Site is Closed to Patient Accruals.

Save

Cancel

- Complete the fields as per the instructions in [Adding Your Site to Abbreviated Trials](#), and then click **Save**.

The system sends you an email message when the CTRO has accepted the trial for registration in the CTRP. If your trial is not *Industrial*, contact the CTRO at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov) to request categorization of the trial as either *National* or *Externally Peer-Reviewed*.

The system synchronizes *Industrial* and *Other* trials currently registered in the CTRP with ClinicalTrials.gov trials every night by comparing their ClinicalTrials.gov Identifiers. The system updates CTRP trial records with the data imported from ClinicalTrials.gov if it finds matching records.

The CTRP system does not import Person information from ClinicalTrials.gov.

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## Registering New Trials

Before you begin to register a trial, ensure that the trial does not exist in the system already by searching for trials using any of the criteria as per the instructions in [Searching for Trials](#). The system uses the Lead Organization ID, Lead Organization Trial ID, and the ClinicalTrials.gov Identifier to detect duplicates. If a duplicate is detected, the system will not record your trial.

### How to Register New Complete Trials

1. On the toolbar, click **Register Trial**, and select your trial's **Submission Category** (funding source) from the drop-down list, either **National**, **Externally Peer-Reviewed**, or **Institutional**.

To read a definition of each of the trial submission categories (study sources), click **View Trial Category Definitions**, click the



) next to each category, or refer to <http://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4>.

The image shows a dropdown menu for the 'Register Trial' button. The menu is open, displaying five options: 'National', 'Externally Peer-Reviewed', 'Institutional', 'Industrial/Other', and 'View Category Definitions'. Each option has a question mark icon to its right. At the bottom of the menu is a 'Batch Upload' button with an upward arrow icon.

The Register Trial page appears.

The image shows the 'Register Trial' form. At the top, there is a heading 'Register Trial' and a subheading 'Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (\*).' Below this, there is a section for 'XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov?' with radio buttons for 'Yes' (selected) and 'No'. A 'Collapse All' button is located below this section. The main form area is divided into two sections: 'Trial Identifiers\*' and 'Other Identifiers'. The 'Trial Identifiers\*' section contains two input fields: 'Lead Organization Trial Identifier:\*' (with a '30 characters left' hint) and 'ClinicalTrials.gov Identifier:'. The 'Other Identifiers' section contains an 'Other Trial Identifier' input field and an 'Add Other Identifier' button.

The system can create an XML document that is formatted to facilitate trial registration with ClinicalTrials.gov. The document it creates contains all the information that you submit during registration and all the trial data abstracted by the CTRO. If you indicate that you do

not need to register the trial with ClinicalTrials.gov, you will not be asked to provide regulatory and responsible party information.

### You can expand and collapse sections of the registration page

By default, all sections of the registration form are displayed.


To collapse or expand each section individually, click the **Collapse** or **Expand** icon on the right side of the section title as shown in the figures below.

To collapse all sections, click **Collapse All**.

## Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (\*).

XML Required, Enable "Upload from NCI CTRP" in [ClinicalTrials.gov](#)? ☒ Yes ☐ No 

 Collapse All

Click to collapse all sections

### Trial Identifiers\*

Click to collapse this section only



Lead Organization Trial Identifier:\*



30 characters left

ClinicalTrials.gov Identifier:



# Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (\*).

XML Required, Enable "Upload from NCI CTRP" in [ClinicalTrials.gov](#)? ☒ Yes ☐ No

+

Expand All

Click to expand all sections

|  |                                   |   |
|--|-----------------------------------|---|
| Trial Identifiers*                             | Click to expand this section only | < |
| Other Identifiers                              |                                   | < |
| Trial Details*                                 |                                   | < |
| Lead Organization/Principal Investigator*      |                                   | < |
| Sponsor/Responsible Party*                     |                                   | < |
| Data Table 4 Information*                      |                                   | < |
| NIH Grant Information (for NIH funded Trials)* |                                   | < |
| Trial Status*                                  |                                   | < |
| Trial Dates*                                   |                                   | < |
| FDA IND/IDE Information for applicable trials  |                                   | < |
| Regulatory Information *                       |                                   | < |
| Trial Related Documents *                      |                                   | < |

2. Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table.

**Tip**  
 Be sure to provide information for all fields marked with an asterisk (\*). If you cannot complete the registration of a trial in one Registration session, you can [save a draft](#) of the trial details you have completed. Later you can return to complete the registration in another session.

Instructions for registering Complete trials

|   |   |
|---|---|
| <b>XML required. Enable "Upload from NCI CTRP" in ClinicalTrials.gov?</b> | If you require an XML document to register your trial with ClinicalTrials.gov, select <b>Yes</b> .<br>If you are not going to submit your trial to ClinicalTrials.gov, select <b>No</b> .<br>The option you select here dictates which sections you will be required to complete. For example, if you select <b>No</b> , you will not be required to complete responsible party and regulatory information. If you select <b>Yes</b> , NCI will be added as a collaborator to the Funding Source. |
|---|---|

|                      |  |
|----------------------|--|
| <b>Various</b>       | <p>Select or enter the appropriate information in the text fields and drop-down lists as appropriate according to the detailed instructions provided for each of the following sections:</p> <ul style="list-style-type: none"> <li>a. <a href="#">Recording Trial Identification Information</a></li> <li>b. <a href="#">Recording Interventional Trial Details</a></li> <li>c. <a href="#">Recording Non-interventional Trial Details</a></li> <li>d. <a href="#">Recording Lead Organizations and Principal Investigators</a></li> <li>e. <a href="#">Recording Sponsors and Responsible Parties</a></li> <li>f. <a href="#">Recording Data Table 4 Information</a></li> <li>g. <a href="#">Recording NIH Grants</a></li> <li>h. <a href="#">Recording Trial Statuses</a></li> <li>i. <a href="#">Recording Trial Dates</a></li> <li>j. <a href="#">Recording INDs and IDEs</a></li> <li>k. <a href="#">Recording Regulatory Information</a></li> <li>l. <a href="#">Recording Trial-Related Documents</a></li> </ul> |
| <b>Save as Draft</b> | <p>Click to save a draft of the record so that you can complete the registration at another time. You must have provided, at the minimum, both the Lead Organization and Lead Organization Trial Identifier to save a draft.</p> <p>The system saves your draft, assigns it a unique ID (for tracking purposes), and sends you an email message confirming that the information has been saved. You can end your Registration session and retrieve your draft later to complete the registration.</p>  |
| <b>Review Trial</b>  | <p>Click to initiate the system check for errors and missing information. The system displays the results in a message at the top of the Review Trial Details page. Indicators mark specific fields that you must complete or correct in order to submit the trial.</p> <p>The Review Trial Details page is read-only. To make changes to the trial data, follow the instructions in <a href="#">Recording Interventional Trial Details</a> and <a href="#">Recording Non-Interventional Trial Details</a>.</p>  |
| <b>Cancel</b>        | <p>Click to cancel the registration. A pop-up message prompts you to confirm cancellation.</p> <div style="border: 1px solid #f0e68c; padding: 10px; margin-top: 10px;"> <p>If you choose to cancel the registration, you will lose all data that you may have entered.</p> </div>   |

3. Correct any errors if indicated, and repeat the previous steps as many times as necessary until the trial is error-free.
  4. To continue with the trial registration, scroll to the bottom of the **Review Trial Details** page, and then click **Submit**. To prevent creating a duplicate record, do not click **Submit** more than once. If you have to make changes after you click **Submit**, contact the CTRO at [ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov) rather than using your browser's Back button to make changes.
- The registration notification message system sends you an email message to acknowledge that the trial has been submitted. Later it sends another email message to notify you when your trial has been accepted or rejected.

After submission, most users other than the trial submitter can not see the trial information you provided until the information has been validated. However, an organization administrator (if one exists) and an assigned owner can access the information prior to validation.

[Return to top of page](#)

## Searching for Organizations

You can search for organizations that are currently registered with the Clinical Trials Reporting Program by any of the following criteria:

- Organization Identifying Information
  - **PO ID** - Enter the exact PO ID only
  - **CTEP ID** - Enter all or part of the CTEP ID
  - **Name** - Enter all or part of the Organization's name
  - **Family Name** - Enter all or part of the Organization Family's name
- Organization Address
  - **Country** - Select the country from the drop-down list
  - **City** - Enter all or part of the organization's primary location
  - **State** - Select the state from the drop-down list
  - **Zip Code** - Enter all or part of the Zip code

- Organization Type. Select one of the following:
  - **Lead Organization** - Returns organizations that are Lead Organizations
  - **Participating Site** - Returns organizations that are Participating Sites
  - **Both** - Returns organizations that are *either* Lead Organizations *or* Participating Sites

## How to Search for Registered Organizations

1. Click the **Search Organizations** tab. Or, on the toolbar, click **Search > Organizations**.

Search Clinical Trials
 Search Persons
 Search Organizations

Enter information for at least one of the criteria and then click Search. The maximum number of results returned for any search is 500 records. If necessary, limit your search by providing additional search criteria.

**Organization Identifying Information**

**Organization Address**

PO ID (Exact Match):

CTEP ID:

Name:

Family Name:

Country:

City:

State:

Zip Code:

Organization Type:  Both

Search

Reset

2. Provide as much information as you can about the organization you are looking for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. You must enter search criteria in at least one field.

### Searching by PO ID

The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

### Using wildcard characters ( % )

You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results. The system adds wildcards on both sides of the search string (the series of letters you type) for you implicitly. You can type wildcard symbols (% or \*) between characters of the string as necessary.

3. Click **Search**.

The organizations that meet your search criteria are listed in the Search Results table. To navigate the search results table, see [Working with Tables and Search Results](#).

Search Clinical Trials
 Search Persons
 Search Organizations
 Search Results

**Organization(s):**

Show 10 entries
 Search: 
 Choose columns

First Previous 1 2 Next Last

| PO-ID                 | CTEP ID | Name                                  | Family Name | City      | State | Country       | Zip   |
|-----------------------|---------|---------------------------------------|-------------|-----------|-------|---------------|-------|
| <a href="#">24827</a> | AK001   | Anchorage Medical and Surgical Clinic |             | Anchorage | AK    | United States | 99501 |
| <a href="#">24856</a> | AK002   | Providence Alaska Medical Center      |             | Anchorage | AK    | United States | 99508 |
| <a href="#">24885</a> | AK003   | Anchorage Radiation Therapy Center    |             | Anchorage | AK    | United States | 99504 |



**Tip**

If the organization you are searching for is not listed, you may have searched too narrowly (that is, you may have provided too much information about the organization). If the list of results is very long and contains many organizations that are similar to the one you are searching for, you can narrow your search by providing more information.

4. If the organization does not appear in the results table, do one of the following to modify your search:
  - To broaden your search so that more organizations are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the organization's name, city, state, and zip code in your original search, you may want to search by state alone.  
- or -
  - To narrow your search so that fewer organizations are listed in the search results, provide more about your organization. For example, if you searched by state in your original search, you may want to search by city in addition to the state.
5. To view the details of any organization in the search results list, click its **PO-ID**.  
The Organization Details window displays current information about the organization, including a live web and/or email link that you can use to contact the organization.

**Organization Details** ×

|                    |   |                |                    |
|--------------------|---|----------------|--------------------|
| <b>Name</b>        | MD Anderson Cancer Center- Bay Area   | <b>PO ID</b>   | 29888347           |
| <b>Family Name</b> | M.D. Anderson Cancer Center   | <b>CTEP ID</b> | TX403              |
| <b>Address</b>     | 18100 Saint John Drive  | <b>Type</b>    | Participating Site |
| <b>City</b>        | Nassau Bay  |                |                    |
| <b>State</b>       | TX  |                |                    |
| <b>Postal Code</b> | 77058   |                |                    |
| <b>Country</b>     | United States   |                |                    |
| <b>Phone</b>       | 713-745-9940  |                |                    |
| <b>Fax</b>         | N/A   |                |                    |
| <b>Email</b>       | N/A   |                |                    |
| <b>Website</b>     | <a href="http://www.mdanderson.org/patient-and-cancer-information/care-centers-and-clinics/regional-care/bay-area/contact-us/index.html">http://www.mdanderson.org/patient-and-cancer-information/care-centers-and-clinics/regional-care/bay-area/contact-us/index.html</a> |                |                    |

[Return to top of page](#)

## Searching for Persons

You can search for persons that are currently registered with the Clinical Trials Reporting Program.

### How to Search for Registered Persons

1. Click the **Search Persons** tab. Or, on the toolbar, click **Search > Persons**.

Search Clinical Trials
 Search Persons
 Search Organizations

Enter information for at least one of the criteria and then click Search. The maximum number of results returned for any search is 500 records. If necessary, limit your search by providing additional search criteria.

PO ID (Exact Match)

Person Role

CTEP ID

Organization Affiliation

First Name

Last Name

- Provide as much information as you can about the person you are looking for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. To search by person role, select a role from the **Person Role** drop-down list. You must enter search criteria in at least one field.

#### Searching by PO ID

The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

#### Using wildcard characters ( % )

You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results.

- Click **Search**.  
The persons that meet your search criteria are listed in the Search Results table. To navigate the search results table, see [Working with Tables and Search Results](#).

Search Clinical Trials
 Search Persons
 Search Organizations
 Search Results

### Person(s):

First Previous 1 2 3 4 5 ... 50 Next Last

Show  entries
 Search:

| PO-ID                  | CTEP ID | First Name | Last Name | Email             | Organization Affiliation   | Role  | City    |
|------------------------|---------|------------|-----------|-------------------|--|---|---------|
| <a href="#">302582</a> | 10192   |            |           | @mdanderson.org   | M D Anderson Cancer Center Cancer Therapy Evaluation Program                                     | Clinical Research Staff Healthcare Provider | Houston |
| <a href="#">317786</a> | 13610   |            |           | @dhs.lacounty.gov | Olive View-University of California Los Angeles Medical Center Cancer Therapy Evaluation Program | Clinical Research Staff Healthcare Provider | Sylmar  |

#### Tip

If the person you are searching for is not listed, you may have searched too narrowly (that is, you may have provided too much information about the person). If the list of results is very long and contains many persons that are similar to the one you are searching for, you can narrow your search by providing more information.

- If the person does not appear in the results table, do one of the following to modify your search:

- To broaden your search so that more persons are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the person's name, city, state, and zip code in your original search, you may want to search by state alone.
  - or -
  - To narrow your search so that fewer persons are listed in the search results, provide more about your person. For example, if you searched by state in your original search, you may want to search by city in addition to the state.
5. To view the details of any person in the search results list, click its **PO-ID** link.
- The Person Details window displays current information about the person.

Person Details

|             |                 |         |  |
|-------------|-----------------|---------|--|
| Prefix      | N/A             | PO ID   | 25976099   |
| First Name  | Test            | CTEP ID | N/A  |
| Middle Name | N/A             |         |  |
| Last Name   | Test            | Role    | Clinical Research Staff<br>Healthcare Provider<br>Organizational Contact |
| Address     | 100 Main Street |         |  |
| City        | Rockville       |         |  |
| Postal Code | 20111           |         |  |
| Country     | USA             |         |  |

Organization Affiliation

3 items found, displaying all items.1

| PO ID                    | Name                      |
|--------------------------|---------------------------|
| <a href="#">154376</a>   | National Cancer Institute |
| <a href="#">9559134</a>  | CTEP_PROD_TEST            |
| <a href="#">18222446</a> | Test Organization         |

6. To view the details of the organization with which the person is affiliated, click its **PO-ID** link.

[Return to top of page](#)

## Searching for Trials

You can retrieve existing trial records once you have registered for an account. See [Creating CTRP Accounts](#).

After you have selected your search criteria, you can further limit or expand your search for trials as follows:

- Use the **Search All Trials** feature to search for all trials registered with the CTRP from all organizations/accounts, whether or not you are the submitter or owner.
- Use the **Search My Trials** feature to search for trials that you own, whether or not your organization is listed as the lead organization or participating site.
- Use the **Search Saved Drafts** feature to search for trials that you have saved as drafts but have not submitted.

The search feature you choose determines which categories of trials will be returned, and the actions you can perform with those results, as shown in the table below. See [Working with Search Results](#) for rules that determine which trial details are displayed.




| Search Option | Search All Trials | Search My Trials | Search Saved Drafts |
|---------------|-------------------|------------------|---------------------|
|---------------|-------------------|------------------|---------------------|

|                                 |  |  |  |
|---------------------------------|--|--|--|
| <b>Types of Trials Returned</b> | All trials   | <ul style="list-style-type: none"> <li>Trials you own that are on hold</li> <li>Trials you own, including those conducted at an affiliated site.</li> </ul>  | Partial Submissions  |
| <b>Actions Permitted</b>        | <ul style="list-style-type: none"> <li>View Trial Details</li> <li>Add/Update My Site (Abbreviated trials only)</li> <li>Verify Trials (for trials you submitted but may not own)</li> </ul> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">                     The results of this search may include a subset of trials that you own or submitted.                 </div> | <ul style="list-style-type: none"> <li>View Trial Details</li> <li>Update Trials</li> <li>Amend Trials</li> <li>Request TSR/XML</li> <li>Change Status</li> <li>Add/Update My Site (Abbreviated trials only)</li> <li>Verify Trials</li> </ul> | <ul style="list-style-type: none"> <li>View Trial Details</li> <li>Complete Submissions</li> <li>Add/Update My Site (Abbreviated trials only)</li> </ul> |

All registered users can search trials with the "Accepted" and subsequent processing status. Additionally, you can search for trials that you own that have not been validated. These trials are indicated by the "Submitted" status. See [Trial Processing Statuses](#) for information about statuses that occur during the course of the trial processing workflow.

## How to Search for Existing Trials

- Click the **Search Clinical Trials** tab. Or, on the toolbar, click **Search > Clinical Trials**. The Search Clinical Trials page appears.

 Search Clinical Trials
 Search Persons
 Search Organizations

Enter information for at least one of the criteria and then click Search. The maximum number of results returned for any search is 500 records. If necessary, limit your search by providing additional search criteria.

**Title:**

**Phase:**

**Pilot Trial?:**

**Identifier Type:**

**Organization Type:**

**Principal Investigator:**

**Purpose:**

**Identifier:**

**Organization:**

**Search By Trial Category:**

🔍 Search
↺ Reset

- Select or enter the appropriate information in the drop-down lists and text fields. (You do not have to select or enter any search criteria if you use the **Search My Trials** feature. When searching **All Trials**, you must select or enter at least one search criterion.) The following table describes the fields.

### Tip

If you are searching for a saved draft, search by **Phase**, **Purpose**, or **Title** only. Because the system adds wildcards for you, do not enter wildcard symbols in the search fields.

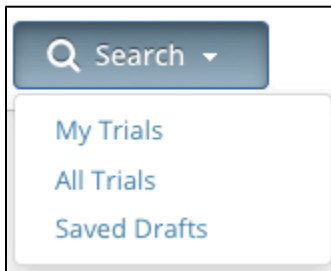
### Trial Search Criteria

| To search by this... | Do this...   |
|----------------------|--|
| <b>Title</b>         | Enter one or more words from the long title or name of the trial provided by the principal investigator or sponsor. <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;"> <p><b>Avoid copying and pasting, or typing the entire title into the search field</b></p> <p>Use keywords rather than phrases or the entire title. Doing so minimizes the potential for excluding from the search results any titles with misspellings or slightly different phrasing.</p> </div> |

|                          |  |
|--------------------------|--|
| <b>Phase</b>             | <p>Select the trial phase from the drop-down menu. Valid values are as follows:</p> <ul style="list-style-type: none"> <li>• <b>0</b> - Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). See FDA guidance on exploratory IND studies for more information.</li> <li>• <b>I</b> - Includes initial studies to determine the metabolism and pharmacologic actions of a medical approach in humans, the side effects associated with increasing doses or exposure, and to gain early evidence of effectiveness; may include healthy participants and/or patients.</li> <li>• <b>I/II</b> - Includes trials that are a combination of phases I and II.</li> <li>• <b>II</b> - Includes controlled clinical studies conducted to evaluate the effectiveness of the medical approach for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.</li> <li>• <b>II/III</b> - Trials that are a combination of phases II and III.</li> <li>• <b>III</b> - Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the medical approach has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.</li> <li>• <b>IV</b> - Studies of FDA-approved drugs, interventions, tests or diagnostic procedures to delineate additional information including the medical approach risks, benefits, and optimal use.</li> <li>• <b>NA</b> (Not applicable) - All non-interventional or pilot studies.</li> </ul> |
| <b>Pilot Trial?</b>      | If the trial is a pilot, select <b>Yes</b> .   |
| <b>Purpose</b>           | <p>Select the primary purpose of the trial from the drop-down list. Valid values are as follows:</p> <ul style="list-style-type: none"> <li>• <b>Treatment</b>. Protocol is designed to evaluate one or more interventions for treating a disease, syndrome, or condition.</li> <li>• <b>Prevention</b>. Protocol is designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.</li> <li>• <b>Supportive Care</b>. Protocol is designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.</li> <li>• <b>Screening</b>. Protocol is designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).</li> <li>• <b>Diagnostic</b>. Protocol is designed to evaluate one or more interventions aimed at identifying a disease or health condition.</li> <li>• <b>Health Services Research</b>. Protocol is designed to evaluate the delivery, processes, management, organization, or financing of health care.</li> <li>• <b>Basic Science</b>. Protocol is designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.</li> <li>• <b>Other</b>. Any purpose not described above.</li> </ul>  |
| <b>Identifier Type</b>   | <p>Select the type of trial identifier from the drop-down list. Valid values are as follows:</p> <ul style="list-style-type: none"> <li>• <b>NCI</b> - NIH National Cancer Institute identifier</li> <li>• <b>ClinicalTrials.gov (ClinicalTrials.gov Identifier)</b> - Provide the <i>exact</i> number, including the ClinicalTrials.gov Identifier prefix. Example: NCT00012345</li> <li>• <b>Lead Organization</b> - Enter the unique identifier assigned to the trial by the lead organization</li> <li>• <b>Other identifier</b> - Additional trial identifier such as unique identifier from other registries, NIH grant numbers, or protocol numbers assigned by the Review Board</li> </ul> <div style="border: 1px solid green; padding: 10px; margin-top: 10px;"> <p><b>Selecting a Trial Identifier Type is not required</b><br/> You can enter an identifier in the <b>Identifier</b> field without first having to choose an Identifier Type.</p> </div>   |
| <b>Identifier</b>        | Enter the unique identifier assigned to the trial by the NCI, ClinicalTrials.gov, PRS, or the identifier assigned to it by the lead organization. For Inter-Group trials, enter the Lead Group's trial number.   |
| <b>Organization Type</b> | <p>Select one of the following organization roles from the drop-down list:</p> <ul style="list-style-type: none"> <li>• <b>Lead Organization</b> - Returns all trials on which the selected organization is the Lead Organization</li> <li>• <b>Participating Site</b> - Returns all trials on which the selected organization is a Participating Site</li> <li>• <b>Both</b> - Returns all trials on which the selected organization is either the Lead Organization or Participating Site</li> </ul> <div style="border: 1px solid green; padding: 10px; margin-top: 10px;"> <p>You can change the Organization Type without affecting any other search criteria you may have selected previously.</p> </div>  |

|                                 |   |
|---------------------------------|---|
| <b>Organization</b>             | <p>The system suggests organizations as you type.</p> <p>Enter the initial letter(s) of the organization and then select the organization from the list of suggestions.</p> <p>To search for trials by organization without having to specify what role the organization plays in the trial, select <b>Both</b> from the <b>Organization Type</b> list, and then select the name of the organization of interest.</p> |
| <b>Principal Investigator</b>   | <p>The system suggests names as you type.</p> <p>Enter the initial letter(s) of the principal investigator's last name and then select the investigator name from the list of suggestions.</p>  |
| <b>Search by Trial Category</b> | To restrict your search by trial category, select <i>Abbreviated</i> or <i>Complete</i> from the drop-down list. Otherwise, select <b>Both</b> .  |

3. Click **Search**.  
The Search menu options are displayed.



4. Do one of the following:
- To search all registered trials in the system, click **All Trials**.  
-or-
  - To search only the trials that you submitted or own, click **My Trials**. This feature enables access to all the trials that you have submitted, including those that are currently on hold. (The Clinical Trials Reporting Office staff places trials on hold when they are unable to process a trial without further information, usually from the submitter.)  
-or-
  - To search only the trials that you have saved for later completion, click **Saved Drafts**.  
-or-
  - To clear all search criteria and begin a new search, click **Reset**.

**Allow sufficient time for the system to conduct your search before you run your search again**

The search is complete only when the system displays search results or alerts you that it could not find a trial to match your search criteria.

The trials that meet your search criteria are listed on the **Search Results** page. For more information on navigating and working with search results, see [Working with Tables and Search Results](#).

Search Clinical Trials

Search Persons

Search Organizations

Search Results

### Clinical Trials Search Results

Show **10**
Search: **thyr**
Choose columns
 << < 1 > >>

| NCI Trial Identifier           | Title   | Current Trial Status | Lead Organization                                 |
|--------------------------------|---|----------------------|---|
| <a href="#">NCI-2013-01471</a> | (*) A Phase I/II Trial of Crolibulin (EPC2407) plus Cisplatin in Adults with Solid Tumors with a Focus on Anaplastic Thyroid Cancer (ATC)   | Active               | NCI - Center for Cancer Research                  |
| <a href="#">NCI-2013-01438</a> | Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma  | Closed to Accrual    | NCI - Center for Cancer Research                  |
| <a href="#">NCI-2011-02530</a> | Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer  | Active               | University of Chicago Comprehensive Cancer Center |
| <a href="#">NCI-2009-01166</a> | A Targeted Phase I/II Trial of ZD6474 (Vandetanib; CAPRELSA) plus the Proteasome Inhibitor, Bortezomib (Velcade), in Adults with Solid Tumors with a Focus on Hereditary or Sporadic, Locally Advanced or Metastatic Medullary Thyroid Cancer (MTC) | Closed to Accrual    | NCI - Center for Cancer Research                  |

Showing 1 to 4 of 4 (filtered from 761 total entries)
 << < 1 > >>

Export options: CSV | Excel

Search Clinical Trials

Search Persons

Search Organizations

Search Results

### Clinical Trials Search Results

Show **10**
Search:
 Choose columns
 << < 1 > >>

| NCI Trial Identifier           | Title  | Current Trial Status | Lead Organization                                   | Lead Org Trial Identifier |
|--------------------------------|--|----------------------|---|---------------------------|
| <a href="#">NCI-2013-02396</a> | (*) Phase II Study of Above-Label Octreotide-LAR in Patients With Insufficiently Controlled Carcinoid Syndrome | Active               | H. Lee Moffitt Cancer Center and Research Institute | MCC 17410                 |

Showing 1 to 1 of 1
 << < 1 > >>

Export options: CSV | Excel

(\*) Trial has alternate titles. Click to view.

Trials may have more than one title. For example, the CTRO staffs may add an alternate title if they find a misspelling in the registered title. Any trial identified by more than one title is identified in the search results table by an asterisk ( \* ) in the Title column.

- To see the alternate titles associated with a trial, click the asterisk (link).  
The list of alternate titles is displayed in the Trial Alternate Titles window.

Search

Register Trial

Administer Trials

Quick Links

Contact Us

Help

Search Clinical Trials

Search Persons

Clinical Trials Search Results

Show 10

| NCI Trial Identifier | Title  |
|----------------------|--|
| NCI-2013-02396       | (*) Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Cancer |

Showing 1 to 1 of 1

Export options: CSV | Excel

(\*) Trial has alternate titles. Click to view.

Trial Alternate Titles

2 items found, displaying all items.1

Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Cancer

Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Cancer

Search Results

Choose columns

<< < 1 > >>

| Status | Lead Organization                                   | Lead Org Trial Id |
|--------|---|-------------------|
|        | H. Lee Moffitt Cancer Center and Research Institute | MCC 17410         |

<< < 1 > >>

**You can change Accrual Disease terminologies for individual trials**  
 If you searched for "My Trials", the search results table displays an additional column, **Accrual Disease Terminology**. You can select a new terminology from the drop-down list only if the trial has *not* accrued patients.

Additionally, you can change accrual disease terminology at any time for trials currently recording accruals at the summary level only.

Clinical Trials Search Results

| Current Trial Status                  | Current Processing Status        | Available Actions | Accrual Disease Terminology                   | Sites |
|---------------------------------------|----------------------------------|-------------------|---|-------|
| Consented to Accrual and Intervention | Accepted                         | Select Action     | SDC   | View  |
| Active                                | Abstraction Verified No Response | Select Action     | --Select--<br>SDC<br>ICD10<br>ICD9<br>ICD-O-3 | View  |
| Completed                             | Accepted                         | Select Action     |   | View  |

- To view a trial, click its **NCI Trial Identifier** link.  
 The Trial Details page appears. See [Viewing Trial Details](#).

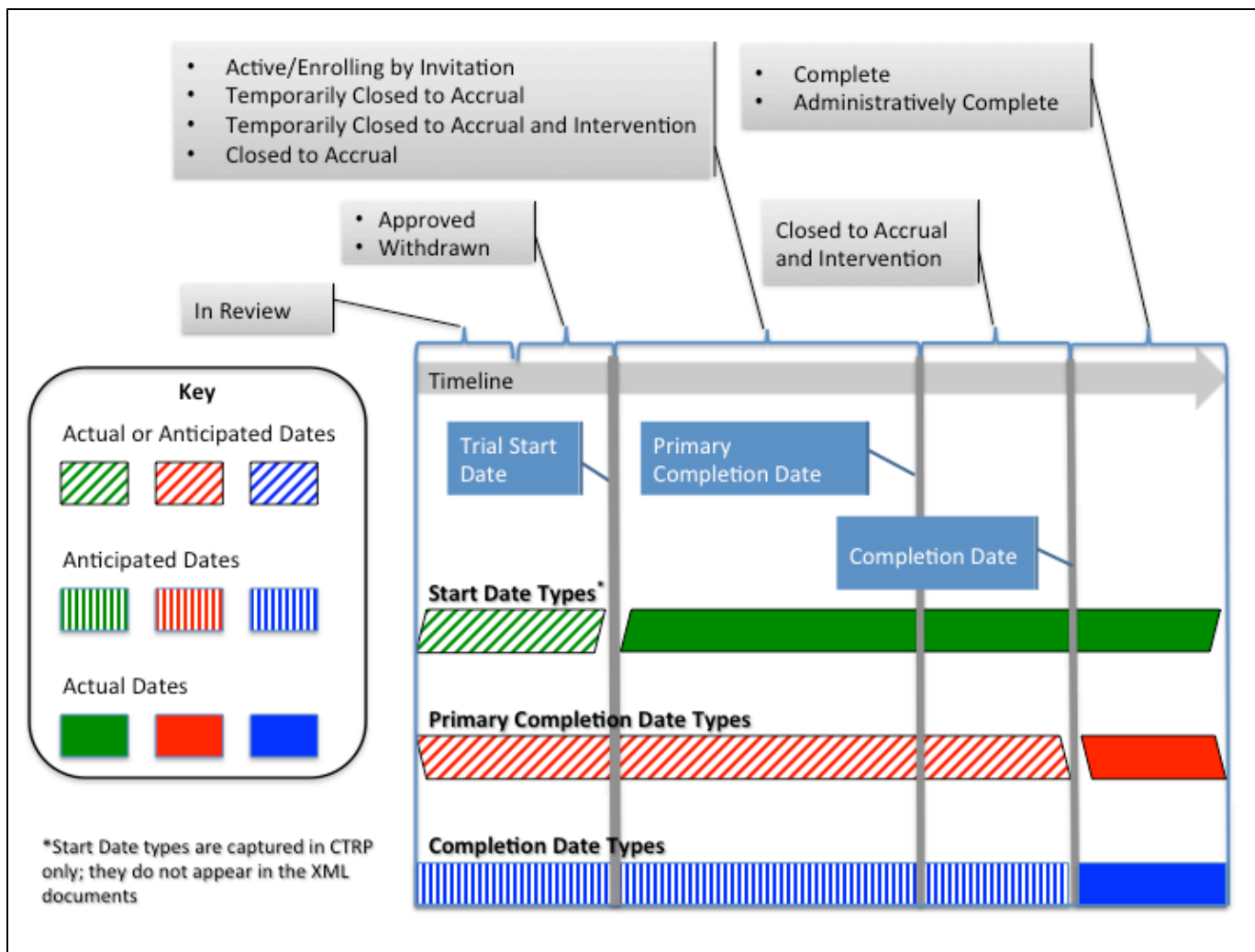
[Return to top of page](#)

### Trial Status Rules for Start and Completion Dates

Valid dates for a given trial status depend on the other values you have entered, and whether those dates are *Actual* (current, or past) or *Anticipated* (future).

The following diagram illustrates these rules. The arrow at the top of the diagram represents a time line for the life of a trial. The three horizontal bands in the lower section of the diagram represent, from top to bottom, the relative date (actual or anticipated) rules for trial Start Date types, Primary Completion Date types, and Completion Date types.





The following table provides the rules for trial status dates as diagrammed.

#### Rules for Status/Dates relationships

| If this is true...   | Follow this rule  |
|--|---|
| Current Trial Status is anything <i>other than</i> In Review, Approved, or Withdrawn | Trial Start Date must be Actual (solid band)                            |
| Current Trial Status is Approved or In Review  | Trial Start Date could be Actual or Anticipated (diagonal stripes band) |
| Current Trial Status is Complete   | All date types must be Actual (solid band)                              |

The general rules for Study Date types are as follows:

- If the date is in the past, the type must be actual.
- If the date is today, the type could be actual or anticipated.
- If the date is in the future, the type must always be anticipated.

The general rules for Study Date values are as follows:

- The Trial Start Date can be in the past, present, or future.
- The Primary Completion Date is always the same as, or later than, the Trial Start Date.
- If the Primary Completion Date is *Actual*, it can be earlier than the Current Trial Status Dates *Complete* or *Administratively Complete*.
- The Completion Date is always the same as, or later than, the Primary Completion Date.

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## Updating Trials

As trial owner, you can update a subset of the information included with the original trial submission, including the following:

- **ClinicalTrials.gov Identifier** (other than Industrial/Other trials)
- **Other Identifier**
- **Local Trial Identifier** (Industrial/Other trials)
- **Title** (other than Industrial/Other trials)
- **Accrual Disease Terminology** (other than Industrial/Other trials)
- **NIH grant information** (for NIH-funded trials).

You can add grants but you can not update existing grant information.

- **Participating site**
  - Site recruitment status and associated date for abstracted trial sites. See [Recording Trial Statuses and Dates](#) .
- **Status dates**

Changing the overall trial status must reflect changes to the trial status at the site. For example, if you change the overall status from Approved to Active, you must change the recruitment status from Not Yet Recruiting to Recruiting.

- **Trial documents**

Documents you upload when using the Update Trial feature do not overwrite existing documents.

You can change the trial status information directly from the Search Results table without having to open the trial record. To use this method, in the Search Results table's **Action** column, select **Change Status** and make your changes as per the instructions in [Recording Trial Statuses and Dates](#) .

## Protocol Document Updates

The Update Trial feature accommodates the following type of protocol document changes.

- **Editorial, Administrative Changes** (correction of minor typographical errors; clarifications made to previously approved descriptions of research)
- **Data, Data Collection, and Data Collection Materials** (revised study diaries; revised questionnaires or QOL surveys given to participants)
- **Recruitment of Subjects** (changes in the way subjects are recruited; a new or revised advertisement)
- **Principal Investigator Contact Information**

### How to Update Trials

1. Click **Search > Clinical Trials**.  
The Search Trials page appears.
2. Click **Search > My Trials**.  
The Search Results table displays the results of your search and actions available (if any) for each record. For information about navigating the search results list, see [Viewing Trial Details](#) .

| Current Processing Status | Available Actions |
|---------------------------|-------------------|
| Accepted                  | Select Action ▼   |
| Abstraction<br>Response   | Select Action ▼   |

Update  
Amend  
Change Status  
View TSR  
View XML  
Verify Data

*"Available Actions" Columns for Complete trials - Select Action List*

| Processing Status        | Available Actions |
|--------------------------|-------------------|
| Update<br>Update My Site | Select Action ▼   |

*"Available Actions" Columns for Industrial trials - Select Action List*

- In the **Available Actions** column, click **Select Action > Update**.  
The Update Trial page displays the data currently registered with CTRP.

## Update Trial

Use this form to update trial information. You can not change the information in certain fields, including the trial title.

 Expand All

### Trial Identifiers\*

Lead Organization Trial Identifier:\* 05-12-3


ClinicalTrials.gov Identifier:

 Add ClinicalTrials.gov Identifier

NCI Trial Identifier: NCI-2014-00314

### Other Identifiers\*

Other Trial Identifier

 Add Other Identifier

### Trial Details\*

Title:\* 18F-FMAU for Imaging in Cancer Patients

Update Trial page for Complete trials

Participating Sites\*

| Organization/Investigator | Local Trial Identifier* | Current Site Recruitment Status* | Current Site Recruitment Status Date* (mm/dd/yyyy) | Date Opened for Accrual (mm/dd/yyyy) | Date Closed for Accrual (mm/dd/yyyy) |
|---------------------------|-------------------------|----------------------------------|--|--------------------------------------|--------------------------------------|
| Case Co                   | THK01Z15                | Approved                         | 09/01/2015   | mm/dd/yyyy                           | mm/dd/yyyy                           |

Existing Trial Related Documents\*

| Document Type | File Name       |
|---------------|-----------------|
| Other         | NCT02524847.xml |

Trial Related Documents\*

Please submit documents as Word (.doc) or Acrobat (.pdf) files.

[Tips for creating CTRP compatible PDF documents](#)

IRB Approval:  No file selected. ?

Informed Consent Document:  No file selected. ?

Other: NCT02524847.xml

Please verify ALL the trial information you provided on this screen before clicking the "Review Trial" button below.  
Once you submit the trial you will not be able to modify the information.

Update Trial page for Industrial trials

An asterisk ( \* ) at the end of a trial title indicates that the trial has alternate titles.

Trial Details\*

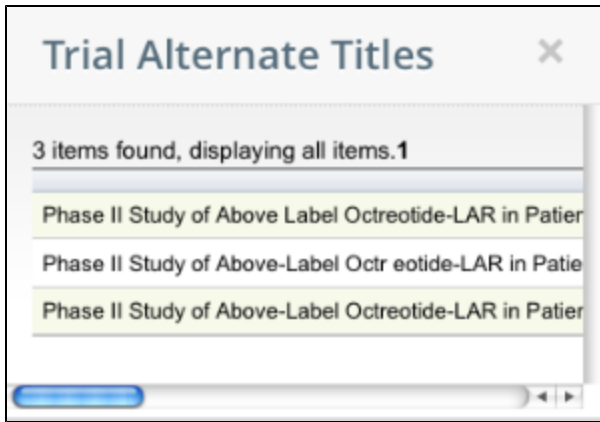
**Title:\***

Alternate Title(s) Indicator

Phase II Study of  
Above-Label  
Octreotide-LAR in Patients  
with Insufficiently  
Controlled Carcinoid

(\*)

- To view the alternate titles, click the asterisk ( \* )



5. If applicable, enter an ClinicalTrials.gov Identifier, and then click **Add ClinicalTrials.gov Identifier**.

You cannot change the ClinicalTrials.gov Identifier once you have added it. If you need to make changes thereafter, contact the CTRO at [NCICTRO@mail.nih.gov](mailto:NCICTRO@mail.nih.gov).

When you submit the trial, the system checks the NCT number you entered to ensure that no other registered trial has the same one. The system displays an error message if it finds another trial with the same NCT number. If this occurs, check the number you entered and try again. If you are certain that the number you entered is correct, contact the CTRO at [NCICTRO@mail.nih.gov](mailto:NCICTRO@mail.nih.gov).

6. Make changes to the fields as necessary. Instructions for recording each of the fields are provided in [Registering New Trials](#).
7. If appropriate, upload any new or updated documents. See [Recording Trial-Related Documents](#).  
If you upload an IRB document, the CTRO reviews the updated record you submit and makes changes to the record as necessary. For example, if you upload an IRB document for a trial currently in the In Review state, the CTRO updates the IRB information section of the trial record (e.g., IRB status and approval number).
8. To review the information you provided, click **Review Trial**.  
The system checks the updated information for errors, and displays the results at the top of the Update Trial page.
9. If necessary, correct any errors, and click **Review Trial**. Repeat this cycle until your update is error-free.
10. Submit the trial update.  
The system sends you an update notification—with the details of what has changed—whenever you update accepted trials.

A trial can accumulate program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you update a trial, the Program Code field displays all codes from the master list for the organization family of the lead organization.

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## Verifying Trial Data

NCI requires that trial owners, trial submitters, and members of the Clinical Trials Reporting Office (CTRO) staff verify their open trial records twice per year to ensure that information is accurate and up-to-date.

This requirement applies to Interventional trials that have the following attributes:

- Trial processing status is either Abstraction Verified - No Response or Abstraction Verified - Response
- Trial status is anything other than the following:
  - Withdrawn
  - Administratively Complete
  - Complete

CTRO staffs are responsible for verifying the types of trials below. Trial owners and submitters are responsible for verifying all others.

- NCI-managed trials (trials with DCP or CTEP IDs)
- NCI-sponsored trials

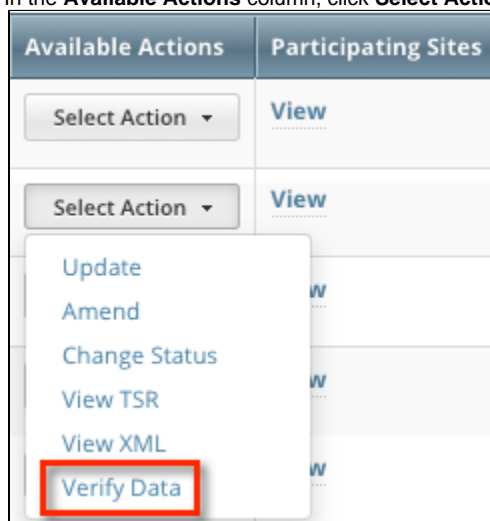
- Trials imported from ClinicalTrials.gov
- Trials submitted by users affiliated with the National Cancer Institute or National Cancer Institute Division of Cancer Prevention
- Trials submitted by the NCI Center for Cancer Research (CCR)

The system sends trial owners, trial submitters, and site administrators a verification reminder 30 and 15 days before their trial data verification due dates. It sends reminders to CTRO staffs 7 days before the due date.

Each time you verify a trial, the CTRP system records your name and date of verification. This is true for original as well as updated trials. You can view these records at any time, but cannot change them.

### How to Access the Trial Data Verification Page

1. Search for the trial by the identifier noted in the email reminder you received, or use the **Search My Trials** feature.
2. In the **Available Actions** column, click **Select Action > Verify Data**.



The Trial Data Verification page appears.

## Trial Data Verification

**NCI Trial Identifier:** NCI-2014-00318  
**ClinicalTrials.gov Identifier:** NCT01804465  
**Lead Organization Trial Identifier:** 12557  
**Title:** A Randomized Phase 2 Trial of Immediate versus Delayed Anti-CTLA4 Blockade Following Sipuleucel-T Treatment for Prostate Cancer Immunotherapy

One item found.1

| Date                    | Verification method           | Verified By |
|-------------------------|-------------------------------|-------------|
| 2014-02-19 10:55:33.322 | Abstraction Verified Response | CTRO Staff  |

### Add Data Verification Record

*I have reviewed the data for this trial :*

Save Verification Record
Cancel

An asterisk ( \* ) at the end of a trial title indicates that the trial has alternate titles.

# Trial Data Verification

NCI Trial Identifier: NCI-2013-02396

ClinicalTrials.gov  
Identifier: NCT01886287

Lead Organization  
Trial Identifier: MCC 17410

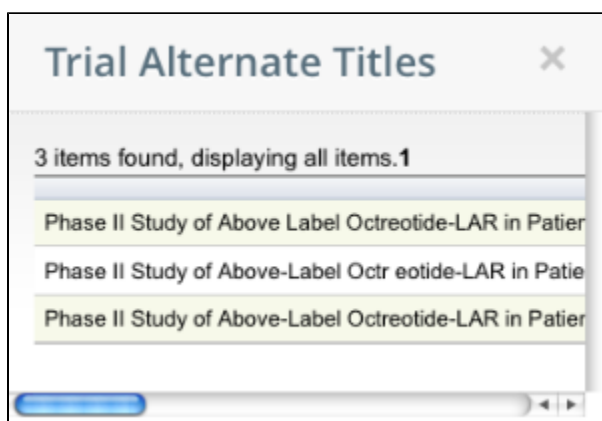
Title: Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently  
Controlled Carcinoid Syndrome (\*)

One item found.1

Alternate Title(s) indicator

| Date                    | Verification method           |
|-------------------------|-------------------------------|
| 2014-01-07 14:40:21.259 | Abstraction Verified Response |

3. To view the alternate titles, click the asterisk ( \* )



## How to Verify Trial Data

1. On the **Trial Data Verification** page, under **Add Data Verification Record**, click **Save Verification Record**.
2. Confirm that you would like to save the record by clicking **OK** in the pop-up message.

The Trial Data Verification page displays all verification records to date.



## Trial Data Verification

**Message:** Record was saved successfully.

**NCI Trial Identifier:** NCI-2014-00318

**ClinicalTrials.gov Identifier:** NCT01804465

**Lead Organization:** 12557

**Trial Identifier:**

**Title:** A Randomized Phase 2 Trial of Pembrolizumab in Combination with Ipilimumab and Radiation in the Treatment of Cervical Cancer Immunotherapy

The system records this when the trial owner or submitter verifies the trial

Trial record owner or submitter

2 items found, displaying all items.1

| Date                    | Verification method           | Verified By    |
|-------------------------|-------------------------------|----------------|
| 2014-04-20 21:31:06.86  | Manual Verification Entered   | Lauren Anthone |
| 2014-02-19 10:55:33.322 | Abstraction Verified Response | CTRO Staff     |

Add Data V

The system records this automatically when the trial has reached the Abstraction Verified Response/No Response processing status

I have reviewed the data for this trial :

 Save Verification Record

 Cancel

[Return to top of page](#)

## Viewing Accrual Assignment History by Trial

As a site administrator, you can view a history of your organization's accrual access assignment on a per-trial basis.

### How to View Accrual Assignment History by Trial

1. On the toolbar, click **Administration > Accrual Access > View**.  
The Accrual Access Assignment by Trial page lists all current access assignments by trial, grouped by trial category.

## Accrual Access Assignment By Trial

### EXTERNALLY PEER-REVIEWED

Show 10

Search:

Choose columns

<< < 1 2 3 4 5 > >>

| NCI Trial Identifier | Title   | Accrual Submitter   |
|----------------------|---|---|
| NCI-2014-00281       | Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions With GM-CSF and Imiquimod | CTRP QATester1<br>Edmond Madaire<br>Isabelle Autissier<br>Rachel Bent<br>Suzanne Arasteh<br>Yael Rubinstein |
| NCI-2014-00248       | Global Proteomic and Phosphoproteomic Profiling of Normal B Cells Isolated From                         | CTRP QATester1  |

### INSTITUTIONAL

Show 10

Search:

Choose columns

<< < 1 2 3 4 5 ... 32 > >>

| NCI Trial Identifier | Title                     | Accrual Submitter   |
|----------------------|---------------------------|---|
| NCI-2014-00508       | Papillary Carcinoma Trial | CTRP QATester1<br>Edmond Madaire<br>Isabelle Autissier<br>Rachel Bent<br>Suzanne Arasteh<br>Yael Rubinstein |

### INDUSTRIAL

Show 10

Search:

Choose columns

<< < 1 2 3 4 5 ... 70 > >>

| NCI Trial Identifier | Title  | Accrual Submitter   |
|----------------------|--|---|
| NCI-2014-00109       | A Phase Ib/II Open-label, Multi-center Study of the Combination of MEK162 Plus AMG 479 (Ganitumab) in Adult Patients With Selected Advanced Solid Tumors | CTRP QATester1<br>Candace Lamm<br>Edmond Madaire<br>Isabelle Autissier<br>Lindsay Synd<br>Rachel Bent<br>Suzanne Arasteh<br>Yael Rubinstein |

Showing 1 to 10 of 691

<< < 1 2 3 4 5 ... 70 > >>

Export options: CSV | Excel

To navigate the table, refer to [Working with Tables and Search Results](#).

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## Viewing Accrual Assignment History in Registration

As a site administrator, you can view a history of your organization's trials to which users have been assigned/unassigned user access.

### How to View Accrual Assignment History

1. On the toolbar, click **Administration > Accrual Access > Assignment History**.  
The Accrual Assignment History page lists all access assignments and assignments.

## Accrual Access Assignment History

Show 10
Search:
Choose columns
<< < 1 2 3 4 5 ... 500 > >>

| Date       | Assignee        | Trial ID       | Assignment Action | Comments     | Assigner |
|------------|-----------------|----------------|-------------------|--------------|----------|
| 06/16/2014 |                 | NCI-2009-00127 | Assigned          |              |          |
| 06/16/2014 |                 | NCI-2009-00130 | Assigned          |              |          |
| 06/16/2014 |                 | NCI-2009-00148 | Assigned          |              |          |
| 06/16/2014 |                 | NCI-2009-00241 | Assigned          |              |          |
| 06/16/2014 |                 | NCI-2009-00254 | Assigned          |              |          |
| 06/16/2014 | Edmond Mulawie  | NCI-2009-00267 | Assigned          |              |          |
| 06/16/2014 | Edmond Mulawie  | NCI-2009-00292 | Assigned          |              |          |
| 06/16/2014 | Edmond Mulawie  | NCI-2009-00635 | Assigned          |              |          |
| 06/17/2014 | Charles Mulawie | NCI-2009-00909 | Unassigned        | unassign all |          |
| 06/17/2014 | Charles Mulawie | NCI-2009-00909 | Assigned          |              |          |

Showing 1 to 10 of 5,000
Export options: CSV | Excel
<< < 1 2 3 4 5 ... 500 > >>

- To navigate the table, refer to [Working with Tables and Search Results](#).
- To export the assignment history to a file, click **CSV** (comma-separated values) or **Excel** in the bottom left corner. Your browser prompts you to open or save the file.

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## Viewing Trial Details

Trials you search for are listed in the Submitted Clinical Trials Search Results table as shown below.

Search Clinical Trials
 Search Persons
 Search Organizations
 Search Results

## Clinical Trials Search Results

Show **10**
 Search: 
 Choose columns
 << < 1 > >>

| NCI Trial Identifier ▼         | Title   | Current Trial Status | Lead Organization                                 |
|--------------------------------|---|----------------------|---|
| <a href="#">NCI-2013-01471</a> | (*) A Phase I/II Trial of Crolibulin (EPC2407) plus Cisplatin in Adults with Solid Tumors with a Focus on Anaplastic Thyroid Cancer (ATC)   | Active               | NCI - Center for Cancer Research                  |
| <a href="#">NCI-2013-01438</a> | Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma  | Closed to Accrual    | NCI - Center for Cancer Research                  |
| <a href="#">NCI-2011-02530</a> | Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer  | Active               | University of Chicago Comprehensive Cancer Center |
| <a href="#">NCI-2009-01166</a> | A Targeted Phase I/II Trial of ZD6474 (Vandetanib; CAPRELSA) plus the Proteasome Inhibitor, Bortezomib (Velcade), in Adults with Solid Tumors with a Focus on Hereditary or Sporadic, Locally Advanced or Metastatic Medullary Thyroid Cancer (MTC) | Closed to Accrual    | NCI - Center for Cancer Research                  |

Showing 1 to 4 of 4 (filtered from 761 total entries)
 << < 1 > >>

Export options: [CSV](#) | [Excel](#)

To view details for a given clinical trial listed on a search results page, click its associated **NCI Trial Identifier** hypertext link. The details provided for a given trial depend on trial ownership (private or public) and [Data Table 4 Category](#) (*Complete* or *Abbreviated*).

The Trial Details page displays the metadata as entered by a trial submitter. The upper part of the Trial Details page is shown below. Refer to the [Glossary of CTRP Terms](#) for a description of the metadata.

## Trial Details

### Trial Identifiers

**NCI Trial Identifier:** NCI-2014-00298

**Lead Organization** M10-338  
**Trial Identifier:**

### Trial Details

**Title:** A Phase 1 Safety and Pharmacokinetic Study of ABT-263 in Combination With Taxotere® (Docetaxel) in the Treatment of Subjects With Solid Tumors

**Phase:** I

**Trial Type:** Interventional

**Primary Purpose:** Treatment

**Secondary Purpose:**

### Lead Organization:


**Lead Organization:** Abbott Laboratories

### Summary 4 Information

**Trial Submission** Industrial  
**Category:**

**Summary 4 Funding** Abbott Laboratories  
**Sponsor/Source:**

**Industrial?** Yes

 [Back to Search Results](#)

Responsible party, IND/IDE, NIH grant information and trial-related documents are only displayed for Private trials.

To return to the **Search Trials** page, scroll to the bottom of the **Trial Details** page, and click **Back to Search Results**.

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## Working with Search Results

The Clinical Trials Reporting Office (CTRO) reviews each trial submitted to the system in order to validate submitted information. During the validation process, the reviewers check for duplicate records and ensure that the submitter has provided all required information. CTRO does one of the following as part of the validation/abstraction process:

- If all data is complete and accurate, the reviewers assign the trial the status "Accepted," and the system notifies the submitter by email.
- If information is missing, or there are discrepancies in the information provided, the reviewers can place a trial on hold. The CTRO contacts the submitter for clarification and/or to request missing documents, and resumes processing once the trial is validated.
- If the trial is a duplicate (i.e., another user has submitted the same trial), the reviewers assign the trial the status "Rejected," and the system sends the submitter an email message indicating the status and reason for the rejection. Reviewers may also reject a trial if CTEP/DCP/CCR has approved the trial. NCI transfers these trials internally.

If you have questions about a rejected trial, contact the [CTRO at ncictro@mail.nih.gov](mailto:ncictro@mail.nih.gov).

The trials that match your search criteria are listed in search results tables. Which of the search results are displayed is determined by the following criteria:

- Processing status of the trial at the time of the search. Trial statuses are listed and defined in [Trial Processing Statuses](#).
  - Submitted** - Original trial submitted but not validated
  - Amendment Submitted** - Amendment submitted but not validated
  - Accepted** - Trial passed validation
  - Rejected** - Trial did not pass validation. These trials are not displayed.
  - Abstracted** - Trial has been abstracted
  - Verification Pending** - Trial has been abstracted, and the Trial Summary Report (TSR) has been sent to the trial submitter for abstraction verification
  - Abstraction Verified Response** - Submitter has verified the abstraction as per the TSR, and has returned feedback to the CTRO within five business days after receiving the TSR
  - Abstraction Verified No Response** - Submitter has not responded or returned verification feedback to the CTRO within five business days after receiving the TSR
- User's role with respect to the trial. User roles include the following:
  - Site Administrator** - Has full access to the trials led by the organization (plays lead organization role)
  - Trial Submitter/Owner** - Has full access to the trials they own or submitted
  - Other user** - Any user other than the trial submitter, owner, or trial's lead organization system administrator
- Trial ownership.** Trial ownership types are as follows:
  - Private trials** - Trials submitted or owned by the user who is currently logged in to Registration
  - Public trials** - Trials submitted by other registered users

(A business day is any weekday that is not a Federal holiday. For a list of Federal holidays, refer to the U.S. Office of Personnel Management's list of [Federal Holidays](#).)

| Show 10   | Search: <input type="text" value="allel"/>  | Choose columns                | <<                                   | <                         | 1                      | > | >>     |
|---|---|-------------------------------|--------------------------------------|---------------------------|------------------------|---|--------|
| NCI Trial Identifier  | Title   | Current Trial Status          | Lead Organization                    | Lead Org Trial Identifier | Principal Investigator |   |        |
| <a href="#">NCI-2014-00260</a>                              | A Phase II Open-Label, Parallel Group Study of Abiraterone Acetate Plus Prednisone in African American and Caucasian Men With Metastatic Castrate-Resistant Prostate Cancer   | Active                        | Duke University Medical Center       | Pro00046383               | George                 |   |        |
| <a href="#">NCI-2012-02535</a>                              | Parallel Phase II Trials of ZD1839 (Iressa®) Alone or Weekly Carboplatin and Paclitaxel followed by ZD1839 (Iressa®) (Oncologists Must Choose) for Metastatic Non-Small Cell Lung Cancer in Patients ≥65 Years of Age | Complete                      | North Central Cancer Treatment Group | N0222                     | Jatoi, A               |   |        |
| <a href="#">NCI-2012-01641</a>                              | Parallel (Randomized) Phase II Evaluation of ARQ 197 and ARQ 197 in Combination with Erlotinib in Papillary Renal Cell Carcinoma  | Temporarily Closed to Accrual | Southwest Oncology Group             | S1107                     | Twardo                 |   |        |
| <a href="#">NCI-2011-02670</a>                              | A Phase III Randomized Trial for Patients with de novo AML Using Bortezomib and Sorafenib (IND#114480; NSC# 681239, NSC# 724772) for Patients with High Allelic Ratio FLT3/ITD  | Active                        | Children's Oncology Group            | AAML1031                  | Aplenc,                |   |        |
| <a href="#">NCI-2009-01104</a>                              | Genome-Wide Association Study (GWAS) for Modifiers of Breast Cancer Risk in BRCA2 Mutation Carriers: Breast Cancer Protective Alleles by Whole Genome Association and Copy Number Analysis                            | Active                        | Gynecologic Oncology Group           | GOG-8010                  | Greene                 |   |        |
| Showing 1 to 5 of 5 (filtered from 7,711 total entries)     |   |                               |                                      |                           | <<                     | < | 1 > >> |
| Export options: <a href="#">CSV</a>   <a href="#">Excel</a> |   |                               |                                      |                           |                        |   |        |

To navigate the search results table, see [Working with Tables and Search Results](#).

Trial records returned from "Search My Trials" and "Search All Trials" options display the following details and actions you can take for each trial when applicable.

No data are displayed for Private trials with a processing status of Rejected nor for Public trials with a processing status of Submitted or Rejected.

The following table describes the columns in the search results table:

| Column                                   | Displayed for Public trials? | Description   |
|--|------------------------------|---|
| NCI Trial Identifier                     | Yes                          | Unique identifier assigned to the trial by the CTRP   |
| Title                                    | Yes                          | Official name of the protocol provided by the study principal investigator or sponsor (same as in the protocol document)  |
| Lead Organization                        | Yes                          | Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial   |
| Lead Org (Organization) Trial Identifier | Yes                          | Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.  |
| Principal Investigator                   | Yes                          | Appointed investigator responsible for conducting the clinical trial, or, for multi-site trials, the study chair  |
| ClinicalTrials.gov Identifier            | Yes                          | Number assigned to the trial by PRS (ClinicalTrials.gov) (for trials that have been submitted to ClinicalTrials.gov previously)   |
| Other Identifiers                        | Yes                          | Identifiers other than Lead Organization Trial Identifier or ClinicalTrials.gov Identifier  |
| Current Trial Status                     | Yes                          | Code that represents the status of a trial in relation to the ability to enroll participants/patients   |
| Current (Trial) Processing Status        | No                           | Stage in the trial processing work flow   |
| Available Actions                        | Yes                          | <p>Actions that are applicable to the trial according to the processing rules</p> <ul style="list-style-type: none"> <li>• Update - Link used to initiate trial updates</li> <li>• Amend - Link used to initiate trial amendments. Available for trials with processing statuses abstraction verified (response/no response).</li> <li>• Change Status - Link used to initiate a change to the trial status and status dates</li> <li>• Add My Site - Link used to initiate adding an organization as a participating site</li> <li>• Update My Site - Link available to Participating Site Record owners to initiate participating site information changes</li> <li>• Request TSR and XML documents (for complete trials) - Documents are sent via email to all trial owners</li> <li>• Verify Trial Data - Link used to verify open trial records twice per year to ensure that information is accurate and up-to-date</li> </ul> <div> <p>The actions available for a trial depend on its processing status and participating site record ownership.</p> </div> |
| Accrual Disease Terminology              | No                           | The disease terminology currently in use for accruals. You can select a new terminology from the drop-down list only if the trial has not accrued patients. Additionally, you can change accrual disease terminology at any time for trials currently recording accruals at the summary level only.   |
| (Participating) Sites                    | Yes                          | One or more organizations participating in the trial. Click <b>View</b> in the <b>Sites</b> column to view participating site details.  |
| Phase                                    | No                           | Phase of the investigation, as defined by the US FDA for trials involving investigational new drug  |
| Primary Purpose                          | No                           | Main purpose of the trial   |
| Category                                 | No                           | Data Table 4 Funding Sponsorship or Trial Submission Category   |
| Trial Start Date                         | No                           | Date on which the trial starts  |
| Responsible Party                        | No                           | Responsible party, as defined by FDAAA  |
| Sponsor                                  | No                           | Primary organization that oversees the implementation of the study and is responsible for data analysis as defined in 21 CFR 50.3   |

|   |    |   |
|---|----|---|
| Data Table 4<br>Funding<br>Sponsor Type | No | Trial category selected for trial submission                        |
| Record<br>Verification Date             | No | Date on which the CTRO validated the trial submission               |
| Submitter                               | No | Name of person who submitted the trial                              |
| Primary<br>Completion Date              | No | Date on which the trial reaches/reached its primary completion date |
| Last Update<br>Submitted                | No | Date on which the trial was last updated                            |
| Last Updater<br>Name                    | No | Name of the person who last updated the trial                       |
| Last<br>Amendment<br>Submitted          | No | Date on which the trial was last amended                            |
| Last Amender<br>Name                    | No | Name of person who amended the trial                                |
| On-Hold Reason                          | No | Reason why the trial was placed on hold                             |

Trial records returned from "Search Saved Drafts" display the following details and actions you can take for each trial when applicable:

| Column                             | Description   |
|------------------------------------|---|
| Temporary Trial Identifier         | Unique identifier that the system assigned to the saved draft   |
| Title                              | Official name of the protocol provided by the study principal investigator or sponsor (same as in the protocol document)  |
| Lead Organization                  | Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial |
| Lead Organization Trial Identifier | Unique identification assigned to the protocol by the sponsoring organization. Multiple studies conducted under the same grant must each have a unique number   |
| Action                             | <ul style="list-style-type: none"> <li>• Complete - Link to initiate trial record completion</li> <li>• Delete - Link to initiate trial deletion</li> </ul>     |

Trial ownership and current processing status determine which of the trial details and actions listed above are displayed in the Search Results table. Refer to [Trial Processing Statuses](#).

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